

## BEST AVAILABLE COPY

### REMARKS

Claims 16-27 are pending in the application.

Claim 16 is amended.

Claim 16 has been amended to correct an error in the structure of component e) provided on Preliminary Amendment of February 22, 2002. The n-butyl groups should each be connected to a nitrogen not a carbon. Support for this amendment is found in the specification, top of page 9.

Claims 16-27 are rejected under 102(e) as being clearly anticipated by Raspanti et al, US Patent No. 5,658,973.

Applicant states in the Preliminary Amendment filed on February 22, 2002 that the combination of Tinuvin 622 and Uvasorb HA 88 is disclosed in the priority document EP 95810042.2 (English translation), filed January 23, 1995. However, the specific structure of component e) of the present claims is not present in the priority document. In order to overcome the US '973 102(e) rejection, Applicant is now providing proof that UVASORB HA 88 available commercially at the time of filing of the EP priority document is defined by the structure of present component e). This proof will provide sufficient basis to invoke the interference which applicant seeks.

The Applicant submits a copy of the Application for Patent Term Extension (PTE) of U.S. Patent No. 4,477,615 filed by 3V on July 12, 1999 and available via Freedom of Information. The PTE application documents the filing and eventual grant of the Food Additive Petition (FAP) for UVASORB HA 88 with the Food and Drug Administration along with a detailed chronology of the FAP from September 16, 1991 thru May 14, 1999. See pages 16 through 39 for the chronology of the UVASORB HA 88 through the FAP process. The PTE application also documents the structure associated with UVASORB HA 88 during this FAP period.

The PTE application effectively identifies the structure (Exhibit A, page 4) associated with the tradename UVASORB HA 88 from the period beginning September 16, 1991 through the grant of the FAP on May 14, 1999 as that identified in the instant component e). As the Applicant filed their priority

document EP 95810042.2 during this time frame (January 23, 1995) and UVASORB HA 88 structure identified in Exhibit A, page 4 is identical to component e), Applicant has proven that UVASORB HA 88 available commercially at the time of filling of the EP priority document is defined by the structure of present component e) and thus overcome the 102(e) rejection.

Reconsideration and withdrawal of the rejection of claims 16-27 is respectfully solicited in light of the remarks and amendment *supra*.

Since there are no other grounds of objection or rejection, passage of this application to issue with claims 16-27 is earnestly solicited. Upon being found allowable, the PTO is respectfully requested to declare an interference between the present application and Raspanti '973.

Applicants submit that the present application is in condition for allowance. In the event that minor amendments will further prosecution, Applicants request that the examiner contact the undersigned representative.

Respectfully submitted,



Tyler Stevenson  
Agent for Applicants  
Reg. No. 46,388

Ciba Specialty Chemicals Corporation  
540 White Plains Road  
Tarrytown, New York 10591  
(914) 785-2784  
SAL\20303\_int.doc

Enclosures: Petition for Extension of Time, Patent Term Extension Application.



**RECEIVED**

THE UNITED STATES PATENT AND TRADEMARK OFFICE

JUL 12 1999

In re U.S. Patent **PATENT EXTENSION**  
**A/C PATENTS**

) Attorney Docket No.: 3V-039  
)

Patentee: Giuseppe RASPANTI et al. )

Issue Date: October 16, 1984 )

Date: *July 9<sup>th</sup> 1999*

**COPY**

**APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 USC 156**

**ATTN: BOX PATENT EXT.**

Honorable Commissioner of Patents and Trademarks  
Washington, DC 20231

This is an application for extension of the term of U.S. Patent No. 4,477,615 (hereinafter referred to as the '615 patent) pursuant to 35 USC 156 and 37 CFR 1.710 *et seq.*, by the owner of the entire interest of the '615 patent, namely, 3V Partecipazioni Industriali S.p.A., Piazzale Principessa, Clotilde, 6 Milan, Italy.

**SECTION A: APPLICATION**

The applicant next provides the specific information required by 37 CFR 1.740(a).

**(1) COMPLETE IDENTIFICATION OF THE APPROVED PRODUCT**

The approved product is 1,3-propanediamine, N,N"-1,2-ethanediylbis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine (UVASORB HA88) as a light stabilizer for polyethylene and polypropylene for food-contact use. The relevant Chemical Abstract Service (CAS) Publication No. 136504-96-6 is attached hereto and incorporated herein. The empirical formula and structural formula, along with IUPAC

nomenclature, Chemical Abstract Service number and Chemical Abstract Service Registry name, are attached hereto as Exhibit A.

(2) **IDENTIFICATION OF THE FEDERAL STATUTE UNDER WHICH THE REGULATORY REVIEW OCCURRED**

The regulatory review occurred under 21 USC §§ 321, 348, 371, and 379 and associated regulations contained in 21 CFR 170, *et seq.*

(3) **IDENTIFICATION OF THE DATE ON WHICH THE PRODUCT RECEIVED PERMISSION FOR COMMERCIAL MARKETING**

UVASORB HA88 was approved by the Food and Drug Administration (FDA) pursuant to the amendment of 21 CFR 178.2010 (antioxidants and/or stabilizers for polymers) to contain reference to HA88 on May 14, 1999. A copy of the final regulation as published in the Federal Register, Vol. 64, No. 93, on May 14, 1999 is attached hereto as Exhibit B.

(4) **IDENTIFICATION OF ACTIVE INGREDIENT OF DRUG PRODUCT**

This subsection of 37 CFR 1.74(a)(4) is not applicable to food additives.

(5) **STATEMENT OF TIMELY FILING OF APPLICATION**

The final regulation was first published in the Federal Register on May 14, 1999. Thus, the last day within the sixty-day period from the date of publication permitted for submission of an application for extension of patent term is believed to be **July 13, 1999.**

(6) **IDENTIFICATION OF PATENT**

The patent for which extension of term is being applied is: United States Patent No. 4,477,615, to inventors Giuseppe Raspanti and Norberto Fossati, filed April 8, 1983, issued October 16, 1984, expires April 8, 2003.

(7) **PATENT COPY**

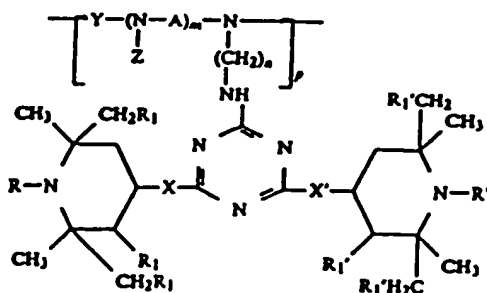
A copy of the above-captioned patent for which an extension of term is being sought, including the entire specification (including claims and drawings) is attached hereto and incorporated herein as Exhibit C.

(8) **DISCLAIMERS/CORRECTIONS/MAINTENANCE FEE RECEIPTS**

No disclaimer of any portion of the term of the present patent has been made. No certificate of correction or reexamination certificate has been requested or issued. Maintenance fee receipts indicating that all required maintenance fees have been paid and that the patent remains in force are attached hereto as Exhibit D.

(9) STATEMENT THAT THE PATENT CLAIMS THE APPROVED PRODUCTClaims of United States Patent No. 4,477,615Uvasorb HA88

## 1. Compounds having the general formula I



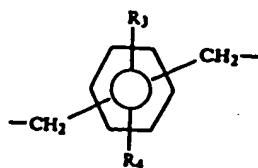
in which R and R' can be the same or different, and represent hydrogen, a straight-chain or branched-chain alkyl radical having 1 to 12 carbon atoms, and alkenyl radical having 3 to 8 carbon atoms, an aralkyl radical having 7 to 19 carbon atoms;

R<sub>1</sub> and R'<sub>1</sub> can be the same or different and represent hydrogen or methyl;

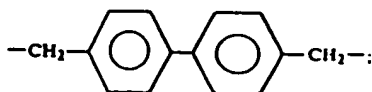
X and X' can be the same or different and represent oxygen or the group N-R<sub>2</sub> in which R<sub>2</sub> represents hydrogen, straight-chain or branched chain alkyl having 1 to 12 carbon atoms, a cycloalkyl radical having 5 to 12 carbon atoms, an aralkyl radical having 7 to 12 carbon atoms;

n can be 2 to 12;

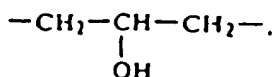
A represents -(CH<sub>2</sub>)<sub>n</sub>-, in which n has the previously defined meaning, the group;



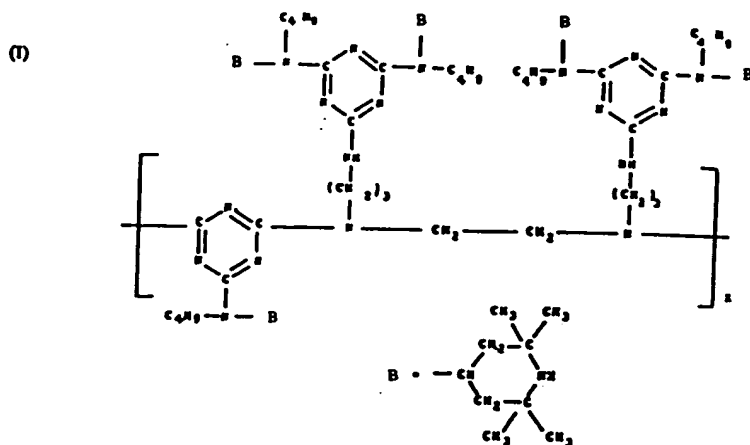
in which R<sub>3</sub> and R<sub>4</sub> are hydrogen or methyl, the group



the group



## 1. Uvasorb HA88 has the following structure



Uvasorb HA88 meets the claim limitations of claim 1 as follows:

R and R' are both hydrogen.

R<sub>1</sub> and R'<sub>1</sub> are both hydrogen.

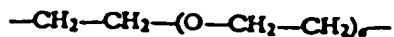
X and X' are N-R<sub>2</sub>, and

R<sub>2</sub> equals butyl.

n equals 2-12.

A represents (CH<sub>2</sub>)<sub>n</sub>

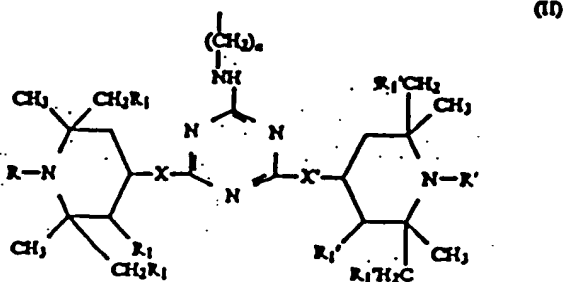
the group



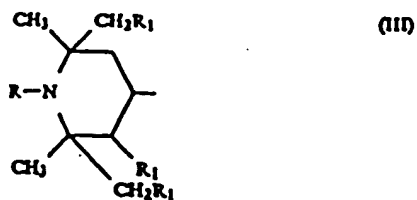
in which  $n$  can be 1-3;

$Z$  represents hydrogen, an alkyl radical having 1 to 18 carbon atoms, a group of formula II

$Z$  is a group of Formula II in which  $R, R', R_1, R'_1, X, X'$  and  $n$  have the above meanings.



in which  $R, R', R_1, R'_1, X, X'$  and  $n$  have the previously defined meaning, or a piperidine group of formula III



$m$  can be equal to zero or 1;

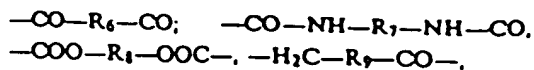
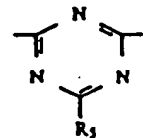
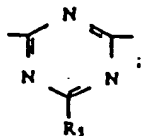
$Y$ , when  $m$  is zero, has the same meaning of  $A$ ;

when

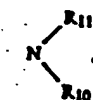
$m$  is 1, can have the same meaning of  $A$  or represent the following groups

$m$  is 1.

$Y$  is the group

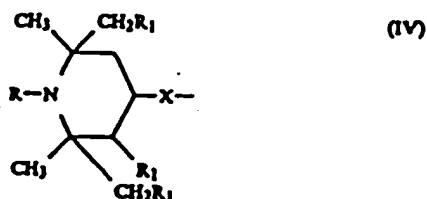


in which  $R_5$  represents hydrogen, a straight-chain or branched alkyl radical having 1 to 18 carbon atoms, a cycloalkyl radical having 5 to 12 carbon atoms, an alkenyl radical having 3 to 18 carbon atoms, an optionally substituted aralkyl radical, having 7 to 19 carbon atoms, an aryl radical having 6 to 12 carbon atoms or the



O- $R_{11}$ , S- $R_{11}$  groups, in which  $R_{11}$  and  $R_{10}$  can be the same or different and represent hydrogen, a straight-chain or branched alkyl radical having 1 to 18 carbon atoms, a cycloalkyl radical having 5 to 12 carbon atoms, an aralkyl radical having 7 to 12 carbon atoms, an aryl radical having 6 to 12 carbon atoms,  $R_{11}$  and  $R_{10}$  together with the nitrogen atom can form a 5 to 7 membered heterocyclic ring; or  $R_5$  represents the piperidine group of formula IV

$R_5$  is the piperidine group of formula IV



in which  $R$ ,  $R_1$  and  $X$  have the previously defined meaning;

$R_4$  represents a bivalent alkylene radical having 1 to 8 carbon atoms, the phenylene radical;

$R_7$  represents a bivalent alkylene radical having 2 to 6 carbon atoms, the tolylene radical, the xylene radical;

$R_8$  represents a bivalent alkylene radical having 2 to 8 carbon atoms;

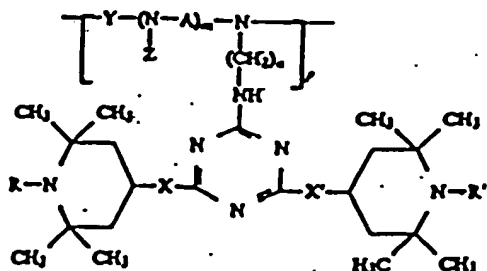
$R_9$  represents an alkylene radical having 1 to 2 carbon atoms or a p-phenylene radical;  
p can vary from 2 to 2000.

wherein  $R$ ,  $R_1$  and  $X$  have the above meanings.

p is in the range 2-2000.



2. Compounds according to claim 1 of formula V

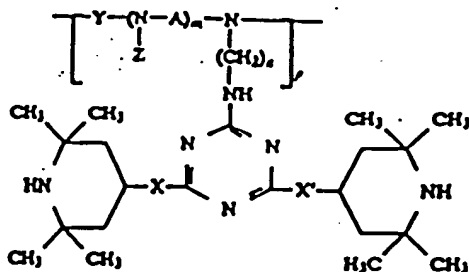


(V)

See claim 1 above. Y, Z, m, n, R, R', X, X' and p have the same meanings as stated above.

in which Y, Z, A, m, n, R, R', X, X', p have the meaning as defined in claim 1.

3. Compounds according to claim 1 of formula X

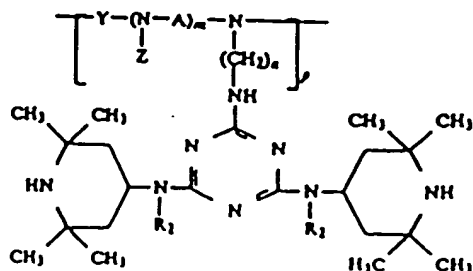


(X)

See claim 1 above. Y, Z, A, m, n, X, X' and p have the same meanings as stated above.

in which Y, Z, A, m, n, X, X' and p have the meaning as defined in claim 1.

4. Compounds according to claim 1 of formula XI

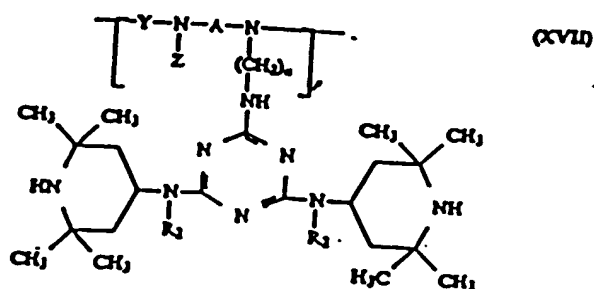


(XI)

See claim 1 above. Y, Z, A, m, n, R<sub>1</sub>, and p have the same meanings stated above.

in which Y, A, Z, m, n, R<sub>2</sub> and p have the meaning as defined in claim 1.

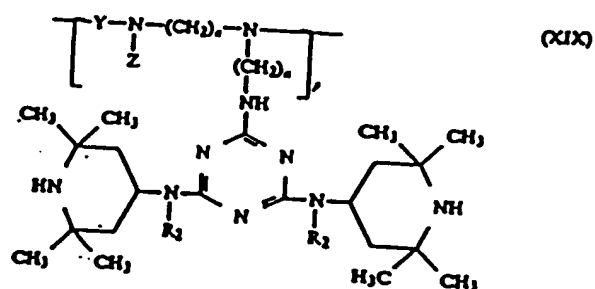
10. Compounds according to claim 1 of formula XVII



See claim 1 above. Y, Z, A, n, R<sub>2</sub>, and p have the same meanings stated above.

in which Y, Z, A, n, R<sub>2</sub> and p have the meaning as defined in claim 1.

12. Compounds according to claim 1 of formula XIX

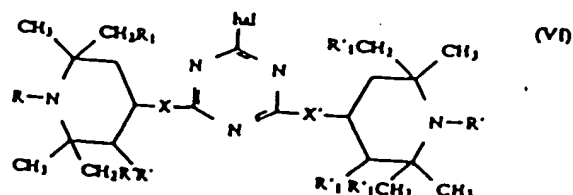


See claim 1 above. Y, Z, A, n, R<sub>2</sub>, and p have the meanings stated above.

in which n can be 2 or 3; Y, Z, R<sub>2</sub> and p have the meaning as defined in claim 1.

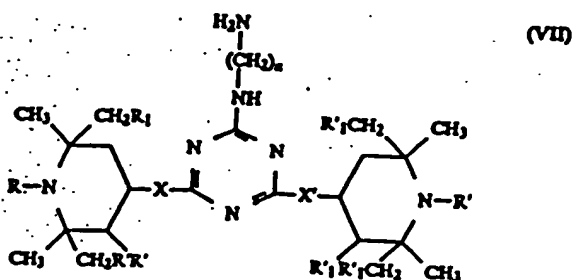
14. A method of preparing compounds having the formula I according to claim 1, characterized in that

(a) one mole of a disubstituted triazine having the formula VI

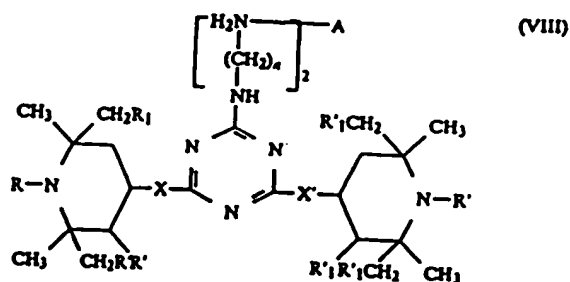


See claim 1 above. This claim covers a method of preparing compounds of formula I, and therefore covers a method of preparing Uvasorb HA88.

is reacted with an excess of a diamine of formula  $H_2N-(CH_2)_n-NH_2$ , to give compound of formula (VII)

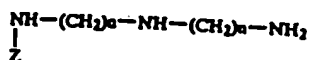


which by subsequent reactions with hal-A-hal, depending on the ratios, give compounds of formula I or intermediates of formula VIII

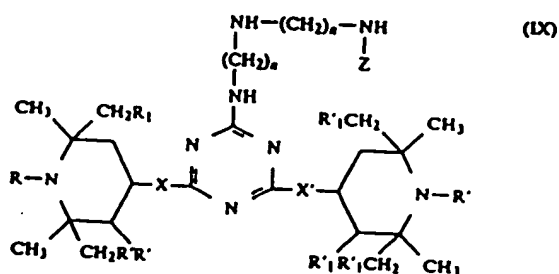


which by their turn, by subsequent reaction with hal-Y-hal give compounds of formula I, or

(b) compound VI is reacted with an amine of formula



to give compounds of formula IX



which, by reaction with hal-Y-hal, give compounds of formula I; the various designations having the meanings as set forth in claim 1.

15. A method of stabilizing a polymer against the deteriorating effects of heat, sunlight and oxygen which comprises incorporating in the polymer an effective amount of a compound according to claim 1.

16. A method according to claim 15 in which the compound according to claim 1 is present in an amount of about 0.01 to about 5.0% on the weight of the polymer.

17. A method according to claim 16 in which the polymer is polyethylene or polypropylene.

15. Uvasorb HA88 is a compound according to claim 1, and is used in a method of stabilizing polymer as claimed.

16. See claim 15, above.

17. See claim 17, above.

USP 4,477,615

- 11 -

Application for Patent Term Extension under 35 U.S.C. Section 156

(10) STATEMENT OF THE RELEVANT DATES AND INFORMATION PURSUANT  
TO 35 U.S.C. 156(g) TO DETERMINE THE REVIEW PERIOD UNDER 37 C.F.R.  
1.740(a)(10)(v)

(a) The date a major health or environmental effects test on the additive was initiated was the date that a P.O. was issued to Springborn Labs., i.e., November 2, 1989. A copy of this P.O. is attached hereto as Exhibit E.

(b) The date on which a petition for product approval under the Federal Food, Drug, and Cosmetic Act was initially submitted was ~~July 12, 1991~~ <sup>September 16, 1991</sup>. The Petition No. was 1B4277.

(c) The date on which the FDA published in the Federal Register notice listing the additive for use was May 14, 1999.

*Lee*  
*July 12<sup>th</sup>, 1999*

(11) **BRIEF DESCRIPTION OF SIGNIFICANT ACTIVITIES UNDERTAKEN BY  
MARKETING APPLICANT DURING THE APPLICABLE REGULATORY  
REVIEW PERIOD WITH RESPECT TO THE APPROVED PRODUCT AND  
SIGNIFICANT APPLICABLE DATES**

3V Partecipazioni Industriali S.p.A., formerly Desitalia Partecipazioni, obtained rights to the '615 patent by merger with Apital Produzioni Industriali S.p.A., to whom the invention was assigned by the inventors. See Section (b)(2) below. The marketing applicant believes that it pursued its activities with due diligence during the regulatory review period. Significant activities undertaken by 3V during the regulatory review period including (1) the testing phase and (2) the approval phase are as follows:

1. Chronology of Uvasorb HA88 Food Additive Petition (FAP) Beginning on the Date a major Health or Environmental Effects Test was initiated (11/02/89) and Ending on the date a petition was initially submitted under the Food, Drug, and Cosmetic Act (09/16/91).

<u>Dates</u>	<u>Activity</u>
11/02/89	P.O. issued to Springborn Labs. (independent testing laboratory) to conduct Migration Study.
11/10/89	3V requests meeting with Dr. Corbin Miles at FDA to review draft FAP.
12/07/89	Meeting between L. Borodinsky and T. Brown of FDA and John Schroer of 3V and Bob Fensterheim of RegNet consultants (independent regulatory consultancy).
12/12/89	Letter to T. Brown of FDA re: meeting.
12/28/89	Letter from T. Brown re: 12/12/89 letter.
01/02/90	Migration study started by Springborn Labs.
03/09/90	First draft migration study issued by Springborn Labs.
03/14/90	Conference call with Judith Haber of Springborn and Bob Fensterheim of RegNet consultants to discuss draft migration report.
03/21/90	Comments by RegNet consultants on first draft report sent to Springborn Labs. with recommendations for improvements.
05/11/90	Second draft migration study report received by 3V. Report studied by Quintini of 3V R&D (Italy), John Schroer of 3V, and Bob Fensterheim of RegNet consultants.
05/16/90	List of information required for Environmental Assessment (EA) received.
05/23/90	Request sent from 3V to 3V R&D (Italy) to supply additional information to complete EA.
05/29/90	Third draft migration study report issued by Springborn Labs.
06/18/90	3V R&D (Italy) supplies information for EA.
06/25/90	Letter from Judith Haber of Springborn Labs. indicating HA88 not detected by UV Vis.
07/05/90	Revised migration study report sent to 3V R&D (Italy) for review and comment.

## Application for Patent Term Extension under 35 U.S.C. Section 156

<u>Dates</u>	<u>Activity</u>
07/13/90	John Schroer of 3V and Bob Fensterheim of RegNet consultants visit Biodynamics (independent contract toxicology lab) to review protocols for toxicity studies and tour laboratory, in conjunction with HA88 study.
07/17/90	3V R&D (Italy) supplies comments on migration study. Quality of work done to that time reviewed.
07/25/90	Springborn Labs. issues revised protocol for migration study.
07/31/90	Springborn Labs. issues agreement to repeat migration study at no cost to 3V.
08/03/90	3V responds to Springborn Labs. on revised protocol.
08/10/90	P.O. issued to Biodynamics to conduct 14-day subchronic rat gavage study re HA88.
08/17/90	Bob Fensterheim of RegNet consultants visits Springborn Labs. to observe validity study and inspect lab.
08/30/90	3V receives analytical data from Springborn Labs. and forwards to 3V R&D (Italy) for review and assistance with methods.
09/07/90	Dosing initiated in 14-day rat study.
09/17/90	3V R&D (Italy) communicates that revised UV Vis. method is under development.
09/21/90	Springborn Labs. proceeding with 8% ethanol extract analysis but holding with 95% ethanol extract studies until improved analytical method available.
10/18/90	Improved UV Vis. analytical method issued by 3V R&D (Italy) and forwarded to Springborn Labs.
10/29/90	3V issues P.O. to Springborn Labs. for additional cost associated with revised method.
02/07/91	Draft revised migration study issued by Springborn Labs. using revised method. Forwarded to 3V R&D (Italy) for review.
02/27/91	Calibration data from Springborn Labs. received and forwarded to 3V R&D (Italy).
03/11/91	Draft report issued by Biodynamics for 14-day rat study.



<u>Dates</u>	<u>Activity</u>
03/25/91	Springborn Labs. completes validity study.
04/01/91	3V receives and forwards validation data to 3V R&D (Italy).
04/09/91	Final report for 14-day rat study issued by Biodynamics.
04/19/91	John Schroer of 3V visits Springborn Labs. to review analytical data and assist in completion of report re HA88.
04/26/91	Draft final report received from Springborn Labs. and forwarded to 3V R&D (Italy).
05/01/91	P.O. issued to Biodynamics for 90-day subchronic rat gavage study.
05/23/91	3V R&D (Italy) supplies comments re: Springborn Labs. final report.
05/23/91	Incorporate results of extraction study into FDA FAP, evaluate exposure assessment, begin work on petition.
07/12/91	3V completes and submits petition to FDA.
07/31/91	FDA acknowledges receipt of FAP.
08/08/91	FDA advises FAP not acceptable as submitted due to confidential information in EA.
08/23/91	3V files revised EA addressing problem of confidential information.
09/16/91	FDA informs 3V that petition is acceptable for filing.

2. The Period between the date the Petition was submitted (09/16/91) and the date the Regulation became Effective (05/14/99).

<u>Dates</u>	<u>Activity</u>
09/16/91	FDA informs 3V that petition is acceptable for filing.
01/03/92	FDA publishes notice (57 Fed. Reg. 291) to the effect that petition is accepted for filing and EA is being reviewed.
01/22/92	FDA issues letter to 3V raising concerns regarding the EA.
02/07/92	3V responds to FDA with revised EA.
02/12/92	FDA publishes new filing date for petition upon receipt of revised EA.
02/12/92 – 09/01/92	FDA reviewing petition. Several attempts made by 3V to determine FAP status during this time period.
09/01/92	FDA issues letter to 3V with questions regarding the chemistry data and migration study submitted with the FAP. Questions forwarded to Springborn Labs.
09/14/92	Received response from Springborn Labs. to FDA migration study questions.
09/22/92	3V informs FDA it intends to respond to all questions issued of 09/01/92 as soon as possible.
09/29/92	Telephone conference with FDA chemists to review questions raised in 09/01/92 letter.
10/09/92	Final 90-day rat gavage subchronic toxicity report issued by Biodynamics.
10/15/92	FDA issues letter to memorialize phone conference of 09/22/92.
10/20/92	3V submits response to chemistry data issues raised in FDA's 09/01/92 letter.

<u>Dates</u>	<u>Activity</u>
10/28/92	Draft migration study protocol sent to Hazelton Lab. (independent contract laboratory for extraction studies) for proposal.
11/02/92	Bob Fensterheim of RegNet consultants discusses migration study protocol issues with Andrew Zajac of FDA.
11/10/92	Hazelton issues proposal for conducting migration study.
11/19/92	P.O. issued to Hazelton to conduct migration study.
12/11/92	Migration study protocol issued by Hazelton.
12/16/92	Experimental phase started in migration study.
01/15/93	Analytical methods used by Hazelton investigated. Questions raised by Hazelton addressed.
01/18/93	Dr. Santoro of 3V R&D (Italy) responds to Hazelton analytical questions.
02/16/93	Hazelton issues draft preliminary validation data.
03/10/93	Hazelton issues draft migration data.
04/01/93	L. Bordinsky of Keller and Heckman law firm (K&H) reviews draft for 3V migration data and issues opinion to extend study to include additional extractions of LDPE.
04/27/93	Additional extractions of LDPE completed by Hazelton. Data reviewed.
05/18/93	Interferences found by Hazelton in 8% ethanol extracts eliminated by filtration.
05/24/93	Hazelton finishes analysis and validation of filtered extracts.
06/01/93	Draft migration study report issued by Hazelton.
06/16/93	3V requests additional spiking and recovery experiments by Hazelton to correct possible deficiency in validity study.
07/06/93	Hazelton completes experimental phase of migration study.
07/16/93	Draft final report issued by Hazelton.
08/05/93	Final migration study report is issued by Hazelton.

<u>Dates</u>	<u>Activity</u>
08/11/93	3V submits amended FAP to FDA including new migration study, exposure assessment, and two additional toxicity studies.
08/18/93	FDA acknowledges receipt of amended FAP and establishes new filing date.
08/18/93-05/19/94	FDA reviews amended FAP. Numerous requests are made by 3V for status report and approval of petition during this period without success.
05/19/94	FDA issues letter to 3V indicating that EA and chemistry reviews were complete and that submitted toxicology data would not support approvals sought by 3V. Additional toxicity data requested.
05/25/94	3V submits additional available toxicity data and requests a meeting with FDA for 06/08/94.
06/30/94	3V representatives meet with FDA officials Tom Brown, Julius Smith, and Drs. Bailey, Lin, and Young. 3V is informed that either an additional 90-day study is required for the current approval request, or the request must be amended to achieve a lower dietary exposure. During meeting, FDA informed 3V that toxicology review was not complete.
07/07/94	Exposure assessment calculations completed for various market approvals and forwarded to 3V R&D (Italy) for decision.
07/15/94	3V files new mutagenicity study with FDA.
07/19/94	FDA acknowledges receipt of study.
07/29/94	3V R&D (Italy) indicates FDA approval should be sought for PP and HDPE, and that LDPE approval should be abandoned.
08/11/94	3V submitted to FDA in accordance with 06/30/94 meeting amended petition seeking approval in HDPE and PP at virtually nil exposure level.
08/17/94	FDA acknowledges receipt of amended FAP.
08/17/94-02/02/95	FDA continues to review toxicity studies, 3V submits numerous requests for status reports, meetings, and approval of the FAP.

<u>Dates</u>	<u>Activity</u>
02/02/95	3V met with FDA officials including Dr. Alan Rulis to review status of toxicology review and FAP approval. 3V informed by FDA that toxicology review was nearly complete and that some questions would be issued in the near future regarding the toxicity data.
02/23/95	FDA issues letter to 3V with toxicology questions. The letter is forwarded to Pharmaco LSR (formerly Biodynamics) for response.
03/14/95	3V submits letter to FDA that it intends to respond promptly to request of 02/23/95.
03/17/95	Pharmaco LSR submits proposal to 3V to respond to questions raised by FDA by means of a peer review of the pathology report of the 90-day study.
03/31/95	P.O. issued to Pharmaco LSR for peer review and response to FDA questions of 02/23/95.
06/30/95	Pharmaco LSR completes peer review and issues response to FDA's 02/23/95 questions.
07/06/95	Response submitted by RegNet consultants to FDA on 3V's behalf.
08/04/95	RegNet requests meeting with FDA to review response to questions and peer review.
08/04/95-11/27/95	FDA reviews 3V's response and rejects request for meeting until enough time has passed to review 3V's response.
11/27/95	FDA officials including Drs. Hattan, Young, Lin, and Mock and 3V representatives meet with Dr. Ward of Pharmaco LSR to review peer review and response to questions. During this meeting, Dr. Hattan indicates that a 90-day rat feeding study would be necessary to answer FDA's continuing concerns.
01/18/96	3V's attorney, Marlene Zarfas, of Reed, Smith, Shaw & McClay law firm (N.Y.C.) issues letter to Dr. Hattan of FDA requesting confirmation of points agreed to in 11/27/95 meeting regarding study protocol.

<u>Dates</u>	<u>Activity</u>
01/26/96	FDA issues memorandum of meeting with additional clarification regarding toxicology study.
02/07/96	FDA issues letter responding to specific protocol questions of Marlene Zarfes.
02/20/96	TAS began review of Pharmaco toxicity data. Comparison of histopathological observations made with pathology report of other similar substance.
03/01/96	Huntingdon Life Sciences (formerly Pharmaco LSR) completes comparison of results of 90-day studies for Uvasorb HA88 and a structurally similar product recently approved by FDA.
03/06/96	TAS completes toxicology report review and recommended that 3V proceed with feeding study.
03/08/96	Analytical method sent to Huntingdon Life Sciences for estimate of dietary analysis methods.
03/22/96	Draft protocol issued by Huntingdon Life Sciences for 90-day feeding study.
03/xx/96	Comment to Huntingdon Life Sciences on draft protocol.
04/11/96	Huntingdon Life Sciences issues final draft protocol for review and submittal to FDA which is forwarded to Marlene Zarfes.
04/16/96	Huntingdon Life Sciences 90-day feeding study protocol submitted to FDA for review.
05/21/96	FDA issues comments to 3V regarding protocol and these are forwarded to Huntingdon Life Sciences.
06/06/96	3V responds to FDA that it intends to proceed with 90-day study and will forward a revised protocol prior to study initiation.
06/24/96	3V submits final protocol for FDA approval.
06/28/96	3V issues contract to Huntingdon Life Sciences to conduct 90-day feeding study.
07/16/96	Huntingdon Life Sciences begins analytical phase of study.

<u>Dates</u>	<u>Activity</u>
09/06/96	After numerous attempts by Huntingdon Life Sciences to perfect method, assistance is requested of 3V on method development.
09/10/96	FDA approves 90-day feeding study protocol.
09/13/96	Telephone conference between B. Middleton of Huntingdon Life Sciences and Dr. Santoro of 3V R&D (Italy) to discuss analytical problems.
09/16/96	Dr. Santoro of 3V R&D (Italy) issues suggestions to Huntingdon Life Sciences to improve results.
09/25/96	Huntingdon Life Sciences transmits analytical data to Dr. Santoro of 3V R&D (Italy) for review.
10/11/96	Additional analytical results sent to 3V R&D (Italy) for review.
10/21/96	Additional analytical results sent to 3V R&D (Italy) for review indicating they cannot meet FDA's criteria established on 05/21/96.
10/23/96	Dr. Quintini of 3V R&D (Italy) suggests a lab visit by Dr. Santoro of 3V R&D (Italy) to review method.
11/07/96	Dr. Santoro of 3V R&D (Italy) and John Schroer of 3V visit Huntingdon Life Sciences lab to review diet preparation and analysis procedures.
11/25/96	Huntingdon Life Sciences issues status report indicating continued problems with analytical method.
12/03/96	New analytical method issued by Dr. Santoro of 3V R&D (Italy) for analysis of diet.
12/19/96	Analytical method validated by Huntingdon Life Sciences.
01/16/97	Homogeneity and stability interim report issued by Huntingdon Life Sciences.
01/28/97	Repeated high dose homogeneity and stability data completed by Huntingdon Life Sciences.
02/11/97	Analytical development phase of Huntingdon Life Sciences study complete.

## Application for Patent Term Extension under 35 U.S.C. Section 156

<u>Dates</u>	<u>Activity</u>
03/25/97	90-day feeding study dosing initiated by Huntingdon Life Sciences.
06/24/97	End of in life phase of study and terminal sacrifice.
09/17/97	Draft toxicology report issued by Huntingdon Life Sciences without analytical section.
10/21/97	Letter from Dr. Villa of 3V R&D (Italy) to Keller and Heckman (K&H) (Brussels) requesting assistance in filing new toxicology data with FDA for existing FAP.
10/23/97	Letter from K&H (Brussels) to K&H (DC) forwarding 10/21/97 letter of 3V R&D (Italy) requesting assistance and requesting firm-wide conflict check.
10/24/97	Letter from K&H (Brussels) to Dr. Villa of 3V R&D (Italy) confirming that K&H will assist 3V with its food-contact projects re: Uvasorb HA88.
10/28/97	K&H prepares memorandum to file re: new client re: Uvasorb.
10/28/97	K&H associate reviews materials sent by client re: Uvasorb.
10/30/97	Letter from Dr. Villa of 3V R&D (Italy) to K&H forwarding an abridged copy of the Uvasorb HA88 FAP.
10/30/97	K&H associate continues review of volumes of documentation on Uvasorb sent by 3V.
10/31/97	Final toxicology report issued by Huntingdon Life Sciences.
11/05/97	Ralph Simmons of K&H contracts to review petition, scientific studies, and prepare and submit amendment of FAP to FDA.
11/05/97	Telephone conference between K&H partner and 3V re: pending FAP on Uvasorb and expediting the same.
11/06/97	Letter from John Schroer of (3V) to K&H forwarding background documentation on the Uvasorb FAP.
11/06/97	K&H staff scientist reviews Uvasorb FAP.
11/06/97	K&H staff scientist reviews Uvasorb FAP.



<u>Dates</u>	<u>Activity</u>
11/10/97	Conference among K&H associate, partner, and staff scientist re: Uvasorb project and reasons for FDA delay of same.
11/11/97	K&H partner reviews documentation of FDA's review of pending Uvasorb FAP.
11/12/97	K&H staff scientist reviews documentation of FDA's review of pending Uvasorb FAP.
11/12/97	K&H works on document management of client materials on Uvasorb.
11/12/97	K&H associate and partner conduct follow-up conference re: Uvasorb status and next steps.
11/13/97	K&H staff scientist reviews background materials on latest 90-day rat study (toxicology data) on Uvasorb.
11/13/97	Telephone conference between K&H (Brussels) and Dr. Villa of 3V R&D (Italy) re: obtaining FDA approval of Uvasorb.
11/14/97	K&H staff scientist reviews all correspondence between 3V and FDA re: pending Uvasorb FAP.
11/17/97	K&H drafts letter to John Schroer of 3V requesting letter to FDA authorizing K&H to act as agent for 3V with respect to the Uvasorb FAP.
11/17/97	K&H staff scientist continues review of data on toxicity of Uvasorb.
11/18/97	K&H prepares and revises draft letter to John Schroer of 3V re: Uvasorb project.
11/18/97	K&H conference including K&H supervising partner re: draft letter to John Schroer of 3V re: Uvasorb.
11/19/97	K&H works on records management of Uvasorb data.
11/20/97	K&H staff scientist reviews new 90-day rat study (toxicology data) provided by 3V.
11/21/97	K&H staff scientist continues review of new 90-day rat study (toxicology data) provided by 3V.

<u>Dates</u>	<u>Activity</u>
11/21/97	Conference between K&H staff scientist and K&H associate re: letter to FDA re: Uvasorb and toxicology data.
11/21/97	K&H partner reviews data submitted by 3V to support Uvasorb FAP.
11/21/97	Conference between K&H partner and associate re: letter to FDA re: Uvasorb and toxicology data.
11/23/97	K&H partner reviews and revises sample letter to FDA authorizing K&H to represent 3V before FDA with respect to the Uvasorb FAP and the letter to John Schroer of 3V forwarding the sample.
11/24/97	K&H staff scientist continues review of toxicity studies of Uvasorb.
11/24/97	K&H staff scientist works on draft letter to FDA to accompany new toxicity study data.
11/24/97	K&H second staff scientist works on safety assessment for Uvasorb as part of preparation of submission to FDA.
11/24/97	K&H associate reviews and revises draft letter to FDA and Uvasorb toxicology assessment.
11/24/97	K&H partner reviews and revises draft submission to FDA re: Uvasorb.
11/24/97	K&H reviews, revises and sends letter to John Schroer of 3V forwarding sample letter of authorization for K&H to act as 3V's agent before FDA on the Uvasorb FAP.
11/25/97	Telephone conference between K&H partner and John Schroer of 3V re: submitting the new toxicology data on Uvasorb to FDA.
11/25/97	K&H paralegal works on preparing submission of new toxicology data to FDA re: Uvasorb.
11/25/97	K&H second staff scientist continues work on safety assessment of Uvasorb.
11/25/97	K&H associate conducts research for and prepares letter to FDA re: Uvasorb FAP.

<u>Dates</u>	<u>Activity</u>
11/26/97	K&H partner reviews and revises letter to FDA submitting additional toxicology studies on Uvasorb and urging prompt action on FAP.
11/26/97	K&H staff scientist continues work re: the submission to FDA re: the Uvasorb FAP.
11/26/97	K&H paralegal works on preparing submission to FDA re: Uvasorb FAP.
11/26/97	Letter from K&H to John Schroer of 3V forwarding draft amendment to 3V FAP for Uvasorb HA88, containing and explaining data from the new toxicology studies and 2 draft proposed regulations.
12/01/97	K&H staff scientist reviews email from John Schroer of 3V commenting on the draft submission.
12/01/97	Telephone conference between K&H staff scientist and John Schroer of 3V.
12/01/97	K&H staff scientist reviews administrative record of the Uvasorb FAP, provided by 3V.
12/01/97	K&H staff scientist revises draft letter to FDA re: Uvasorb FAP.
12/01/97	K&H associate reviews and works on response to comments of John Schroer of 3V on the draft submission to FDA.
12/01/97	K&H associate conducts additional research for the submission to FDA on the pending Uvasorb FAP.
12/01/97	K&H partner reviews comments from John Schroer of 3V re: the draft submission to FDA on the Uvasorb FAP.
12/02/97	K&H partner continues work on draft submission to FDA re: Uvasorb FAP.
12/02/97	K&H staff scientist continues revising draft letter to FDA re: Uvasorb FAP, in light of comments of John Schroer of 3V.
12/03/97	Email from K&H associate to John Schroer of 3V re: receipt of volumes of additional toxicity study data.

<u>Dates</u>	<u>Activity</u>
12/03/97	K&H associate reviews newly received volumes of additional toxicity study data on Uvasorb.
12/03/97	K&H partner continues work on draft submission to FDA re: Uvasorb FAP.
12/04/97	K&H associate continues review of newly received volumes of additional toxicity study data on Uvasorb.
12/04/97	K&H associate continues revising draft submission to FDA re: Uvasorb FAP.
12/04/97	Scientific conference among 3 K&H staff scientists re: consumption factor and other issues for the pending Uvasorb FAP.
12/04/97	K&H staff scientist continues drafting and revising letter to FDA re: the Uvasorb FAP.
12/04/97	K&H partner continues work on draft submission to FDA re: Uvasorb FAP.
12/05/97	Conference between K&H staff scientist and second K&H staff scientist re: scope of proposed clearance for Uvasorb and dietary exposure calculations for same.
12/05/97	Telephone conference between K&H staff scientist and John Schroer of 3V re: scientific data for continued preparation of the submission to FDA on the pending Uvasorb FAP.
12/05/97	Conference between K&H partner and staff scientist re: submission to FDA on Uvasorb.
12/05/97	K&H associate continues preparation of overall submission to FDA re: Uvasorb FAP.
12/05/97	K&H paralegal works on preparing submission on Uvasorb FAP for filing with FDA.
12/08/97	K&H staff scientist continues work on draft submission to FDA re: the Uvasorb FAP.
12/08/97	K&H associate revises draft letter to FDA (part of primary submission of amendment to Uvasorb FAP).

<u>Dates</u>	<u>Activity</u>
12/08/97	K&H associate drafts letter to FDA to accompany the overall submission on the FAP.
12/08/97	K&H partner signs letters to FDA.
12/08/97	K&H files amendment to Uvasorb FAP with FDA, including 2 new toxicology studies and 2 proposed orders (draft regulations).
12/09/97	K&H associate does follow-up work on 12/08/97 filing of submission to FDA re: the pending Uvasorb FAP.
12/10/97	Letter from FDA to K&H acknowledging FDA's receipt of the substantive amendment to the Uvasorb FAP and notifying that FDA is establishing new filing data for the FAP accordingly.
12/12/97	FDA reviews amended FAP. Several requests for status reports are made at various levels in the FDA by K&H.
12/18/97	K&H receives FDA acknowledgement of filing on the Uvasorb FAP.
12/18/97	K&H associate drafts letter to John Schroer of 3V re: FDA acknowledgement of submission on the Uvasorb FAP.
12/19/97	K&H associate revises letter to John Schroer of 3V re: FDA acknowledgement of filing of additional toxicological studies and K&H explanatory letter in support of the Uvasorb FAP.
12/19/97	K&H partner reviews and revises letter to John Schroer of 3V re: FDA acknowledgement of filing of additional toxicology studies and K&H explanatory letter in support of the Uvasorb FAP.
01/07/98	Telephone conference between 3V and K&H re: status of contacting FDA re: expediting the Uvasorb FAP and re: K&H preparing a letter on expectation of favorable FDA action.
0/07/98	K&H associate drafts letter to 3V re: prediction of favorable FDA resolution of Uvasorb FAP.

<u>Dates</u>	<u>Activity</u>
01/08/98	Conference among K&H staff scientist, second K&H staff scientist, and K&H associate re: preparing letter to 3V re: favorable outlook on the Uvasorb FAP.
01/08/98	K&H second staff scientist works on letter to 3V re: expectation of favorable outcome on FAP.
01/08/98	K&H associate continues work on letter to 3V re: expectation of favorable outcome on FAP.
01/08/98	K&H associate researches and otherwise prepares for telephone conference with FDA re: the Uvasorb FAP.
01/09/98	Conference between K&H staff scientist and K&H associate re: potential FDA concerns re: the Uvasorb data.
01/09/98	K&H associate revises draft letter to 3V.
01/09/98	K&H associate prepares for telephone conference with FDA re: FAP.
01/12/98	K&H partner reviews and revises letter to John Schroer of 3V re: prospects for FDA approval of the Uvasorb FAP.
01/12/98	K&H associate revises letter to John Schroer of 3V re: prospects for FDA approval of the Uvasorb FAP.
01/13/98	Telephone conference between K&H associate and John Schroer of 3V re: Uvasorb FAP.
01/13/98	K&H associate continues revising letter to John Schroer of 3V re: prospects for FDA approval of the Uvasorb FAP.
01/13/98	K&H partner reviews and revises letter to John Schroer of 3V re: prospects for FDA approval of the Uvasorb FAP.
01/15/98	Telephone conference between K&H associate and John Schroer of 3V re: draft letter on favorable outlook on the Uvasorb FAP.
01/15/98	K&H associate drafts cover letter to John Schroer of 3V to accompany letter re: favorable outlook of the Uvasorb FAP.

<u>Dates</u>	<u>Activity</u>
01/15/98	K&H partner reviews and revises letters to John Schroer of 3V re: prospects for FDA approval of the Uvasorb FAP (including cover letter accompanying same).
01/16/98	FDA Consumer Safety Officer (CSO) inquiry to K&H re: certain exposure data in the Uvasorb FAP.
01/16/98	Telephone conference among K&H partner, K&H associate, and FDA CSO re: prospects for expedited review of the new data provided on the Uvasorb FAP.
01/16/98	Telephone conference between K&H and John Schroer of 3V following up on K&H's telephone conference with FDA CSO.
01/16/98	K&H staff scientist revises exposure calculation in response to FDA inquiry on exposure data.
01/30/98	Letter from K&H to John Schroer of 3V forwarding bills for work performed in November and December 1997 and confirming that K&H will continue to press for favorable review of the Uvasorb FAP at FDA.
02/11/98	K&H associate drafts letter to John Schroer of 3V re: notice of amendment to Uvasorb FAP printed in Food Chemical News.
02/11/98	K&H sends John Schroer of 3V an additional copy of the amendment to the FAP filed on 12/08/97.
02/13/98	K&H sends letter to John Schroer of 3V re: notice in Food Chemical News re: the Uvasorb FAP.
03/05/98	Telephone conference among K&H associate, K&H staff scientist, and John Schroer of 3V re: status of the Uvasorb FAP.
03/05/98	K&H conference re: telephone conference with John Schroer of 3V and next steps for ensuring clearance of Uvasorb FAP.
03/05/98	Email from K&H associate to K&H partner and file summarizing telephone conference with John Schroer of 3V.
03/06/98	Conference between K&H associate and FDA CSO re: Uvasorb FAP status.

<u>Dates</u>	<u>Activity</u>
03/06/98	Conference among K&H associate, K&H partner, and K&H staff scientist updating on conference with FDA CSO re: Uvasorb FAP status.
03/09/98	Telephone conference between K&H and John Schroer of 3V re: status of FAP pending at FDA.
03/13/98	Letter from FDA to K&H notifying that FDA is extending the scientific review period of the FAP for an additional 90 days.
03/25/98	Conference between K&H staff scientist and K&H associate re: progress of Uvasorb FAP.
03/26/98	Telephone conference between John Schroer of 3V and K&H associate re: status of Uvasorb FAP.
03/27/98	Telephone conference among John Schroer of 3V, the Vice President of 3V, and K&H associate re: status of Uvasorb FAP.
03/30/98	Conference between K&H staff scientist and K&H associate re: advising 3V about status of pending Uvasorb FAP.
03/31/98	K&H conferences to map out status of pending Uvasorb FAP.
04/02/98	Conference between K&H partner and K&H associate re: status of Uvasorb FAP at FDA.
04/07/98	K&H receives letter from FDA indicating that FDA is extending the review period for the FAP.
04/07/98	K&H associate drafts letter to John Schroer of 3V re: FDA's extension of the review period for the Uvasorb FAP.
04/10/98	Telephone conference between K&H partner and Andy Zajac (FDA) re: expediting the evaluation of the additional toxicology information submitted with the amendment to the FAP on 12/08/97.
04/10/98	Conference between K&H associate and K&H partner re: implications of FDA's extension of the review period for the Uvasorb FAP.



<u>Dates</u>	<u>Activity</u>
04/10/98	K&H partner reviews draft letter to John Schroer of 3V notifying of and explaining implications of FDA's extension of the review period for the Uvasorb FAP.
04/22/98	Telephone conference between K&H partner and Andy Zajac (FDA) re: expediting the evaluation of the additional toxicology information submitted with the amendment to the FAP on 12/08/97.
04/22/98	Conference and email between K&H associate and K&H partner and conference between K&H associate and K&H scientist re: status of Uvasorb FAP pending at FDA.
04/27/98	Telephone conference between K&H associate and FDA CSO re: status of Uvasorb FAP.
04/27/98	Telephone conference between K&H partner and Mitch Cheeseman (FDA) re: expediting FDA's review of 3V's additional toxicology studies.
04/27/98	Telephone conference between K&H and John Schroer of 3V following up on K&H conferences with FDA.
04/28/98	Telephone conference among K&H partner, K&H associate, and John Schroer of 3V re: status of Uvasorb FAP at FDA and conferences with FDA officials re: same.
05/15/98	Telephone conference between K&H and Mitch Cheeseman (FDA) re: status of expedited review of 3V's additional toxicology studies.
05/18/98	Telephone conference between K&H and John Schroer of 3V re: status of FDA review of Uvasorb FAP.
05/28/98	Telephone conference between K&H associate and FDA CSO re: status of Uvasorb FAP.
05/28/98	Telephone conference among K&H partner, K&H associate, and John Schroer of 3V re: no need to submit eye irritation studies on Uvasorb to FDA and re: status of K&H contacts with FDA on ensuring progress of FAP.

<u>Dates</u>	<u>Activity</u>
06/01/98	Telephone conference between K&H partner and Laura Tarantino (FDA) re: expediting review of Uvasorb FAP.
06/01/98	K&H leaves voicemail message for John Schroer of 3V re: K&H conference with FDA.
06/03/98	Telephone conference between K&H partner and John Schroer of 3V re: status of pending Uvasorb FAP and available steps to expedite review.
06/09/98	Telephone conference between K&H and Laura Tarantino (FDA) re: status of FDA review of the Uvasorb FAP.
06/12/98	K&H reviews letter from German BgVV clearing Uvasorb HA88, sent by John Schroer of 3V.
06/12/98	K&H sends BgVV letter on Uvasorb to K&H (Brussels) for translation.
06/15/98	Conference between K&H associate and K&H (Brussels) scientist re: translating letter from BgVV re: Uvasorb HA88 and publication of amendment to Recommendation III accordingly.
06/15/98	K&H (Brussels) reviews and translates German BgVV letter clearing Uvasorb HA88.
06/16/98	K&H associate and K&H (Brussels) staff scientist exchange voicemail messages re: translation of BgVV letter and publication of corresponding amendment to Recommendation III.
06/17/98	K&H (Brussels) continues work on translating German BgVV letter clearing Uvasorb HA88.
06/17/98	K&H partner and K&H associate exchange voicemail messages re: status of Uvasorb FAP at FDA and K&H (Brussels) work translating German BgVV clearance for Uvasorb.

<u>Dates</u>	<u>Activity</u>
06/19/98	Email exchange between K&H and K&H (Brussels) staff scientist re: obtaining a copy of the BgVV journal publishing the amendment to Recommendation III of BgVV acceptance of Uvasorb HA88.
06/22/98	K&H (Brussels) staff scientist researches listings of the BgVV, specifically forthcoming publication of Uvasorb clearance.
06/22/98	K&H associate works on drafting translation of the BgVV letter accepting Uvasorb HA88 for use with all polyethylenes and letter to FDA forwarding and explaining the translation.
06/29/98	K&H (Brussels) staff scientist reviews BgVV requirements and sends email to K&H associate re: testing requirements for polyethylenes under Recommendation III.
06/29/98	Telephone conference between K&H (Brussels) and BgVV re: BgVV's clearance of Uvasorb HA88 and the publication of same.
06/30/98	K&H (Brussels) staff scientist reviews and revises translation of BgVV clearance of Uvasorb HA88 in consideration of submitting the translation to FDA in support of the FAP.
07/10/98	K&H partner reviews voicemail message from Mitch Cheeseman (FDA) re: status of the toxicological review of the Uvasorb FAP.
07/10/98	K&H associate revises letters to FDA forwarding the translation of the BgVV letter of acceptance of Uvasorb.
08/24/98	Telephone conference between K&H partner and Mitch Cheeseman (FDA) re: status of FDA review of the Uvasorb FAP.
09/10/98	Telephone conference between K&H partner and FDA re: FDA's successful completion of the toxicology review for the Uvasorb FAP.
09/10/98	Telephone conference between K&H partner and John Schroer of 3V re: FDA's successful completion of the toxicology review for the Uvasorb FAP.

<u>Dates</u>	<u>Activity</u>
09/10/98	K&H prepares letter to John Schroer of 3V re: FDA's successful completion of the toxicology review for the Uvasorb FAP and implications of same.
09/11/98	K&H reviews, revises, and sends letter to John Schroer of 3V re: FDA's successful completion of the toxicology review for the Uvasorb FAP and implications of same.
09/18/98	K&H associate prepares memorandum to the file summarizing recent developments at FDA re: the Uvasorb FAP, specifically the favorable completion of the toxicology review and K&H's notification of John Schroer of 3V re: same.
09/18/98	Email exchange between K&H partner and K&H associate re: decision to refrain from sending the BgVV clearance letter to FDA at this time so as to not seem overly aggressive about the Uvasorb FAP.
10/15/98	Telephone conference between K&H associate and FDA CSO re: status of pending Uvasorb FAP.
10/15/98	K&H associate leaves voicemail message for Mitch Cheeseman (FDA) re: status of pending Uvasorb FAP.
10/15/98	Telephone conference between K&H associate and John Schroer of 3V re: contacts with FDA on the Uvasorb FAP and the delay at FDA re: completion of the Uvasorb final toxicology memorandum.
10/15/98	Telephone conference between K&H associate and K&H partner, updating K&H partner on contacts with FDA re: status of Uvasorb FAP.
10/15/98	K&H associate drafts memorandum to file as record of day's conferences with FDA.
10/23/98	Telephone conference between John Schroer of 3V and K&H partner re: status of the Uvasorb FAP.

<u>Dates</u>	<u>Activity</u>
10/23/98	Email exchange between K&H partner and K&H associate re: follow-up on contacts with Mitch Cheeseman (FDA) re: FDA's treating the Uvasorb FAP as a high priority now.
10/29/98	Telephone conference between K&H partner and FDA CSO re: final toxicology memorandum due to be completed by FDA within 1 week.
11/06/98	K&H leaves voicemail message for FDA CSO re: Uvasorb FAP status.
11/06/98	Telephone conference between K&H associate and Mitch Cheeseman (FDA) following up on the status of the Uvasorb FAP.
11/06/98	Conference between K&H staff scientist and K&H associate re: toxicity review of Uvasorb by FDA.
11/06/98	Telephone conference between K&H associate and John Schroer of 3V re: status of the FAP under review at FDA.
11/06/98	K&H associate prepares memorandum to file summarizing contacts with FDA re: status of pending Uvasorb FAP.
11/16/98	Telephone conference among K&H partner, John Schroer of 3V, and Mitch Cheeseman (FDA) re: extent of coverage of draft regulation being prepared by FDA for Uvasorb, i.e., which polymers will be covered for the Uvasorb application.
12/14/98	Telephone conference among K&H partner, John Schroer of 3V, and FDA re: FDA preparation of the draft regulation for Uvasorb.
01/19/99	Conference between K&H associate and FDA CSO re: status of pending Uvasorb FAP draft regulation.
01/19/99	K&H leaves detailed voicemail message for John Schroer of 3V re: conference with FDA CSO re: status of the draft regulation for Uvasorb.
02/05/99	Telephone conference between FDA CSO and K&H partner re: change in CAS No. for Uvasorb HA88.

<u>Dates</u>	<u>Activity</u>
02/05/99	Email exchange and telephone conferences among K&H partner, K&H staff scientist, and K&H associate re: research necessary for responding to FDA's inquiry re: change in CAS No. for Uvasorb HA88.
02/05/99	K&H associate drafts letter to FDA confirming change in CAS No. for Uvasorb HA88.
02/05/99	K&H paralegal works on letter to FDA confirming change in CAS No. for Uvasorb HA88.
02/09/99	Letter from K&H to FDA CSO confirming that Uvasorb CAS No. has changed and confirming that FDA has prepared a draft regulation for Uvasorb.
02/18/99	FDA issues preliminary draft food additive regulation with request for updated environmental assessment (EA).
02/18/99	Letter from FDA to K&H forwarding FDA's draft regulation clearing Uvasorb and requesting confirmation that the EA submitted as part of the FAP is current.
02/18/99	K&H faxes draft regulation and letter from FDA to John Schroer of 3V.
02/18/99	K&H staff scientist reviews draft regulation on Uvasorb provided by FDA.
02/18/99	Letter from FDA to K&H acknowledging receipt of 02/09/99 filing re: the CAS No. change for Uvasorb.
02/25/99	Letter from 3V to K&H forwarding draft revised EA for submission to FDA and confirming the suitability of the draft regulation provided by FDA.
03/01/99	K&H reviews and revises the revised EA submitted by 3V.
03/01/99	Conference between K&H staff scientist and K&H supervising partner re: revisions to EA sent by 3V.
03/01/99	Telephone conference between K&H associate and John Schroer of 3V re: 3V's revisions to the Uvasorb EA.
03/01/99	K&H paralegal works on drafting letter to FDA filing the revised EA.

<u>Dates</u>	<u>Activity</u>
03/01/99	K&H partner and K&H associate review and revise draft letter to FDA filing the revised EA for Uvasorb.
03/02/99	Letter from K&H to John Schroer of 3V forwarding draft letter to FDA filing the revised EA for Uvasorb for his review prior to filing with FDA.
03/03/99	K&H paralegal works on revising the submission and otherwise preparing the filing of the revised EA to be filed with FDA.
03/02/99	K&H files letter confirming agreement with the draft regulation for Uvasorb and submitting the revised EA, updating the company name, the CAS No. for Uvasorb, and the certification statement in the EA.
03/02/99	K&H associate leaves voicemail message for FDA CSO following up on filing.
03/02/99	K&H sends confirmation of filing to John Schroer of 3V.
03/03/99	K&H associate leaves voicemail message for FDA CSO following up on submission and requesting a mailed (not faxed) copy of the draft regulation, as requested by John Schroer of 3V.
03/03/99	Letter from FDA to K&H acknowledging FDA's receipt of 03/02/99 submission (revised EA and agreement with draft regulation).
03/04/99	K&H associate follows up with FDA on filing of confirmation of draft regulation and revised EA.
03/16/99	Email from K&H associate to K&H partner, inquiring as to whether FDA CSO had returned call.
03/16/99	K&H associate works on management of the Uvasorb FAP records, following the recent submissions to FDA.
03/18/99	K&H associate leaves voicemail message for FDA CSO inquiring into the status of the forthcoming final regulation and confirming that FDA found the recent submissions from K&H and 3V to be in order.
03/30/99	K&H receives mailed copy of draft regulation from FDA.

<u>Dates</u>	<u>Activity</u>
03/30/99	Email from K&H associate to K&H partner notifying that FDA CSO has called and draft regulation is now awaiting final internal FDA steps before publishing.
03/31/99	K&H partner responds to K&H associate's 03/30/99 email and K&H partner and K&H associate discuss next steps re: Uvasorb regulation.
03/31/99	K&H mails to John Schroer of 3V a copy of the draft regulation received via U.S. mail from FDA.
03/31/99	Telephone conference between K&H third staff scientist and FDA re: administrative processing of the draft to final regulation.
03/31/99	Email exchange among K&H partner, K&H associate, and K&H third staff scientist re: ongoing chain of events to ensure forthcoming publication of Uvasorb regulation.
03/31/99	K&H arranges to have paralegal check advanced Federal Register daily to look for publication of Uvasorb regulation.
04/09/99	K&H associate researches Federal Register for expected final rule on Uvasorb and notifies K&H partner on same.
04/09/99	K&H partner leaves message for FDA CSO re: status of final regulation awaiting publishing in Federal Register.
04/09/99	K&H partner leaves message for John Schroer of 3V re: status of final regulation still awaiting publishing in Federal Register.
05/04/99	Dr. Villa of 3V R&D (Italy) inquires of K&H as to when the final regulation for Uvasorb will be published.
05/04/99	K&H associate sends email responding to Dr. Villa of 3V R&D (Italy), stating that 3V's Uvasorb regulation has likely been delayed due to FDA's publishing its drug regulations en masse the past several weeks.
05/12/99	K&H associate researches status of Uvasorb final regulation awaiting publishing in the Federal Register.



<u>Dates</u>	<u>Activity</u>
05/13/99	K&H paralegal researches FDA publishing final rule on Uvasorb in Federal Register and notifies K&H associate that the rule apparently is slated to be published on 05/14/99.
05/13/99	K&H does follow-up research on paralegal's report that Uvasorb final regulation is likely scheduled to be published on 05/14/99.
05/13/99	Telephone conference between K&H and John Schroer of 3V notifying 3V that Uvasorb final regulation is apparently scheduled to be published on 05/14/99.
05/14/99	Final FDA regulation clearing Uvasorb published in Federal Register.
05/14/99	K&H sends copies of final published regulation to John Schroer of 3V and Dr. Villa of 3V R&D (Italy).

(12) **STATEMENT OF ELIGIBILITY FOR EXTENSION, LENGTH OF EXTENSION  
CLAIMED AND HOW LENGTH OF EXTENSION WAS DETERMINED**

Applicant believes that the '615 patent is eligible for patent term extension pursuant to 35 U.S.C. 156 for the following reasons:

- (a) The term of the patent has not expired before this application is being submitted.
- (b) The term of the patent has never been extended.
- (c) This application for patent term extension is submitted by an authorized agent of the record owner of the '615 patent.
- (d) The product has been subject to a regulatory review period before its commercial marketing or use as evident from paragraph 11 above.
- (e) The permission for the commercial marketing or use of the product after regulatory review is the first commercial marketing or use of the product under the provision of FFDCA.

Applicant believes that the '615 patent is entitled to 1,827 days of term extension. This length of extension is calculated according to 37 C.F.R. Section 1.776, and details of the calculation are provided on the Patent Office Worksheet, attached hereto as Exhibit F. The date on which a major Environmental Effects test was initiated was November 2, 1989. The date on which a petition was initially submitted was September 16, 1991. The date the Regulation became effective was May 14, 1999.

(13) **STATEMENT ACKNOWLEDGING DUTY TO DISCLOSE TO THE  
COMMISSIONER OF PATENTS AND TRADEMARKS AND THE SECRETARY  
OF HEALTH AND HUMAN SERVICES ANY INFORMATION WHICH IS  
MATERIAL TO THE DETERMINATION OF ENTITLEMENT TO THE  
EXTENSION SOUGHT**

Applicant acknowledges the duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

(14) **PRESCRIBED FEE**

The fee prescribed for receiving and acting upon the application for extension under 37 C.F.R. Section 1.20(i), namely One Thousand One Hundred Twenty Dollars (\$1,120.00) is attached hereto.

(15) **CORRESPONDENCE ADDRESS**

The name address and telephone number of the person to whom inquiries and correspondence relating to the application for patent term extension are to be directed is as follows:

Joerg-Uwe Szipl, Esq.  
Griffin, Butler, Whisenhunt & Szipl, LLP  
2300 Ninth St., South, Arlington VA, 22204  
Tel. No. (703) 979-5700  
Fax No. (703) 979-5700

(16) **DUPLICATE OF THE APPLICATION PAPERS**

A duplicate of the application papers is certified to be attached hereto.

(17) **OATH OR DECLARATION SET FORTH IN 37 C.F.R. 1.740(b)**

The declaration set forth in 37 C.F.R. 1.740(b) follows.

USP 4,477,615

- 42 -

Application for Patent Term Extension under 35 U.S.C. Section 156

SECTION B: DECLARATION UNDER 37 CFR 1.740(B)

I, ANTONIO SECCOMANI hereby declare:

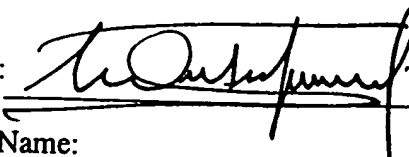
1. That I am an official of the corporate owner of United States Patent 4,477,615, namely, 3V Partecipazioni Industriali S.p.A., Piazzale Principessa, Clotilde, 6 Milan, Italy, authorized to obligate the corporation.
2. 3V Partecipazioni Industriali S.p.A. Piazzale Principessa, Clotilde, 6 Milan, Italy, is the owner of record in the above captioned patent as evidenced by the following documents attached hereto as Exhibit G: The Assignment transferring all interest in U.S. Patent No. 4,477,615 from assignee Apital Produzioni Industriali S.p.A., Milan Italy, owner of record of the '615 patent at the time of issuance; a copy of an Extract of the Registry of Companies of the Chamber of Commerce, Bergamo, Italy, reflecting the merger of the above assignee into Desitalia Partecipazioni; and official records reflecting a change of name from Desitalia Partecipazioni to present assignee 3V Partecipazioni Industriali S.p.A.
3. I have reviewed and understand the contents of this application pursuant to 35 U.S.C. 156 and 37 C.F.R. 1.740, for extension of United States Patent No. 4,477,615. Attached hereto as Exhibit H, are copies of 35 U.S.C. 156 and 37 C.F.R. Sections 1.710, 1.720, and 1.740.
4. I believe that United States Patent No. 4,477,615 is subject to extension pursuant to 37 C.F.R. ~~1.740~~ 1.710.
5. I believe that an extension of the length claimed in the present application is justified under 35 U.S.C. 156 and the applicable regulations.

*Ant*  
July 12, 1989

6. I believe that the patent for which the extension is being sought meets the conditions for extension of the term of patent as set forth in 37 C.F.R. Section 1.720;

7. I acknowledge the duty to disclose to the Commissioner of Patents and trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

8. I further declare that all statements made herein of my own knowledge are true; that all statements made on information and belief are believed to be true; that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of this application.

Signed:  Title: President & CEO Date: July 9th 1999  
Typed Name: ANTONIO SECCOMANDI

**EXHIBIT LIST**

- A: Identification of UVASORB HA88 by  
IUPAC Nomenclature, CAS Registry Number and Name,  
Trade Name and Synonyms, and  
Empirical Formula, Structural Formula and Molecular Weight
- B: Final FDA Regulation approving UVASORB HA88  
as published in the Federal Register, Vol. 64, No. 93,  
dated May 14, 1999
- C: U.S. Patent No. 4,477,615
- D: Maintenance Fee Receipts for U.S. Patent No. 4,477,615
- E: P.O. Issued November 2, 1989 to Springborn Labs
- F: Patent Office Worksheet calculating Term Extension Period
- G: Ownership Records
- H: 35 U.S.C. 156  
37 C.F.R. 1.710, 1.720 and 1.740

IUPAC Nomenclature: Poly[[6-[(2,2,2,6-tetramethyl-4-piperidinyl) (butyl) imino]-s-triazine-2,4-diyl] [(2,4 bis- (N-(2,2,6,6-tetramethyl-4-piperidinyl)butylamino)1,3,5-triazinyl-6-propylamino)-imino], 1,3,5-ethylene[(2,4 bis (N-2,2,6,6 tetramethyl-4-piperidinyl) butylamino 1,3,5-triazine-6-yl-propylamino)-imino]]

CAS #: 136504-96-6

CAS Registry Name: 1,3-Propanediamine, N,N''-1,2-ethanediylbis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine (9CI)

FILE

A.2 - Trade Name and Synonyms

Trade Name: UVASORB HA88

Denomination Used for

Some Toxicology Studies: TABANOL 4

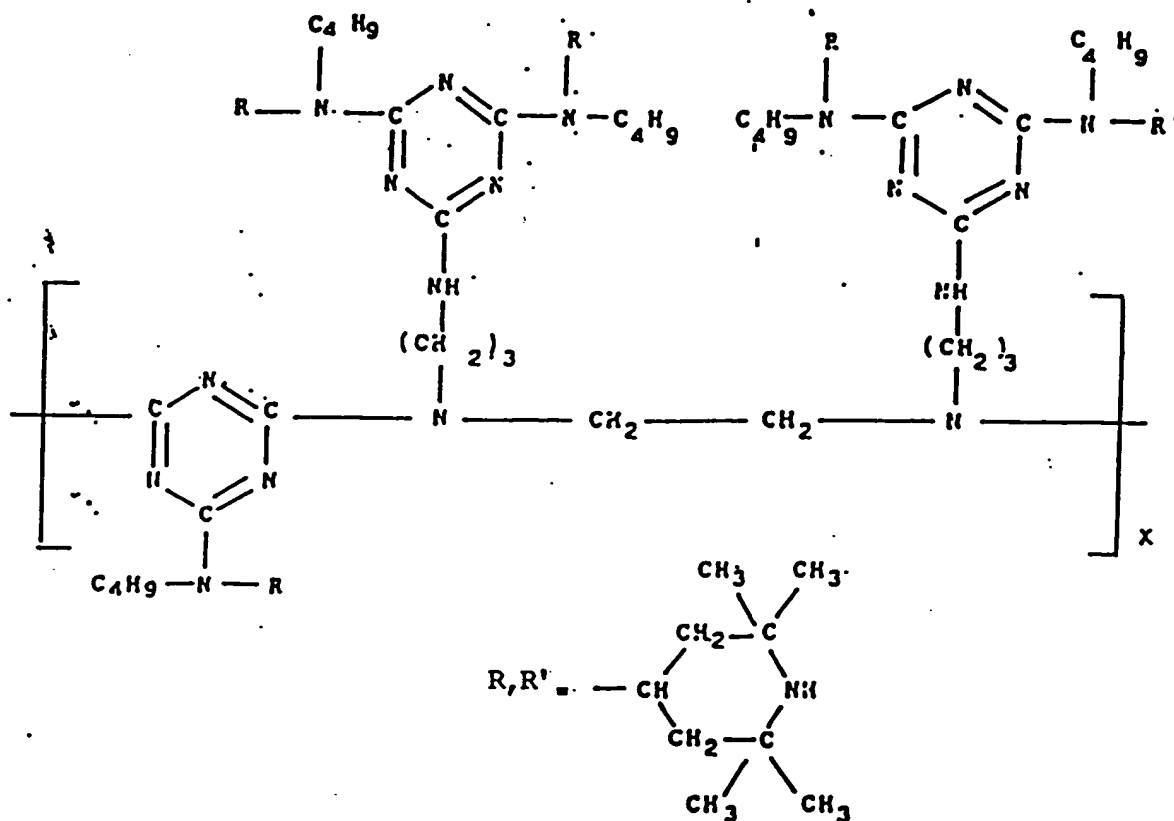


A.3 - Empirical Formula, Structural Formula and Molecular Weight

Empirical Formula:  $(C_{82}H_{153}N_{23})_x$

Structural Formula:

CONFIDENTIAL



Molecular Weight:

- Highest number average molecular weight detected:  
3200 (Osmometric method)
- Lowest number average molecular weight detected:  
2900 (Osmometric method)

## SIZE STANDARDS BY SIC INDUSTRY

SIC code and description	Size standards in number of employees or millions of dollars
DIVISION I—SERVICES	
7389 Business Services, N.E.C. Except, Map Drafting Services, Mapmaking (Including Aerial) and Photogrammetric Mapping Services.	\$5.0 \$4.0
8711 Engineering Services Military and Aerospace Equipment and Military Weapons Contracts and Subcontracts for Engineering Services Awarded Under the National Energy Policy Act of 1992. Marine Engineering and Naval Architecture	\$4.0 \$20.0 \$20.0
8712 Architectural Services (Other than Naval)	\$13.5
8713 Surveying Services	\$4.0 \$4.0

Aida Alvarez,  
Administrator.

[FR Doc. 99-12267 Filed 5-13-99; 8:45 am]  
BILLING CODE 8328-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 178

(Docket No. 91F-0399)

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 1,3-propanediamine, N,N'-1,2-ethanedithiolbis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine as a light stabilizer for polypropylene and polyethylene complying with 21 CFR 177.1520. This action responds to a petition filed by 3-V Chemical Corp.

**DATES:** The regulation is effective May 14, 1999. Submit written objections and requests for a hearing by June 14, 1999. **ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Julius Smith, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3091. **SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of January 3, 1992 (57 FR 291), FDA announced that a petition (FAP 1B4277) had been filed by 3-V Chemical Corp., P.O. Box Drawer Y, Georgetown, SC 29442, proposing to amend § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010), to provide for the safe use of 1,3-propanediamine, N,N'-1,2-ethanedithiolbis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine as a light stabilizer for polyethylene and polypropylene complying with 21 CFR 177.1520.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will have the intended technical effect, and

therefore, that the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before June 14, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in

support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 178

Food additives, Food packaging. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and

Applied Nutrition, 21 CFR part 178 is amended as follows:

### PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding an entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

(b) \* \* \*

#### Substances

#### Limitations

1,3-Propanediamine, N,N'-1,2-ethanediylbis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidamine and 2,4,6-trichloro-1,3,5-triazine (CAS Reg. No. 136504-66-6).

#### For use only:

1. At levels not to exceed 0.3 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1, 1.2, and 1.3.
2. At levels not to exceed 0.2 percent by weight of olefin polymers having a density greater than or equal to 0.94 grams per cubic centimeter and complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, and 3.2.
3. At levels not to exceed 0.3 percent by weight of olefin polymers having a density less than 0.94 grams per cubic centimeter and complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, and 4.0. The finished polymers are to contact food only under conditions of use B through H described in Table 2 of § 178.170(c) of this chapter, and when used in contact with fatty foods of Types III, IV-A, V, VII-A, and IX as described in Table 1 of § 178.170(c) of this chapter, the finished articles are to have a volume of at least 18.9 liters (5 gallons).

Dated: May 3, 1999.  
L. Robert Lake,  
Director, Office of Policy, Planning and  
Strategic Initiatives, Center for Food Safety  
and Applied Nutrition.  
(FR Doc. 99-12177 Filed 5-13-99; 8:45 am)  
BILLING CODE 4160-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

#### 21 CFR Part 640

[Docket No. 98N-0608]

Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human)

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood

derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. FDA is issuing these amendments directly as a final rule because the agency believes they are noncontroversial and that there is little likelihood that there will be comments opposing the rule. Elsewhere in this issue of the Federal Register, FDA is publishing a proposed rule under FDA's usual procedures for notice and comment in the event the agency receives any significant adverse comments. If any significant adverse comment is received sufficient to terminate the direct final rule within 30 days after the comment period ends, FDA will consider such comments on the proposed rule in developing the final rule. FDA is issuing this rule as



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D. C. 20231

WALTER H. SCHNEIDER  
P.O. BOX 917  
DUBLIN, OH 43017

DATE MAILED  
10/28/87

031140

Continued from page 1 of 1  
Continuation of the fee statement  
for the patent listed below

## MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 10, "status" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 10, "status" below. An explanation of the codes appears on the reverse of the Maintenance Fee Statement. **TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).**

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. **THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.**

ITH NBR	PATENT NUMBER	FEE CODE	FEE AMOUNT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY. SHL YR ENT	STAT
1	4,477,615	273	225	----	06/483,092	10/16/84	04/08/83	04 YES	PAID

If the "status" column for a patent number listed above does not indicate "PAID" a code or an asterisk (\*) will appear in the "status" column. Where an asterisk (\*) appears, the codes are set out below by the related item number. An explanation of the codes indicated in the "status" column and as set out below by the related item number appears on the reverse of the maintenance fee statement.

ITH  
NBR  
1  
ATTY DKT  
NUMBER  
1579

DIRECT THE RESPONSE TOGETHER WITH PART B OF THIS NOTICE, AND ANY QUESTIONS ABOUT THIS NOTICE TO:  
COMMISSIONER OF PATENTS AND TRADEMARKS, BOX M. FEE, WASHINGTON, DC 20231



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D. C. 20231

WALTER H. SCHNEIDER  
P.O. BOX 917  
DUBLIN, OH 43017

DATE MAILED  
11/09/91

177679

## MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 10, "status" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 10, "status" below. An explanation of the codes appears on the reverse of the Maintenance Fee Statement. **TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).**

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. **THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.**

ITM NBR	PATENT NUMBER	FEE CDE	FEE AMOUNT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT
1	4,477,615	274	835	----	06/483,092	10/16/84	04/08/83	08	YES	PAID

If the "status" column for a patent number listed above does not indicate "PAID" a code or an asterisk (\*) will appear in the "status" column. Where an asterisk (\*) appears, the codes are set out below by the related item number. An explanation of the codes indicated in the "status" column and as set out below by the related item number appears on the reverse of the maintenance fee statement.

ITM NBR	ATTY DKT NUMBER
1	1579

DIRECT THE RESPONSE TOGETHER WITH ANY QUESTIONS ABOUT THIS NOTICE TO:  
COMMISSIONER OF PATENTS AND TRADEMARKS, BOX M. FEE, WASHINGTON, DC 20231



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D. C. 20231

75M3/0417

WALTER H. SCHNEIDER  
5715 STRATHMORE LANE  
DUBLIN, OH 43017

## MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 10, "status" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 10, "status" below. An explanation of the codes appears on the reverse of the Maintenance Fee Statement. TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.

ITM NBR	PATENT NUMBER	FEE CODE	FEE AMOUNT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY SML YR ENT	STAT
1	4,477,615	285	1495	----	06/483,092	10/16/84	04/08/83	12 YES	PAID

If the "status" column for a patent number listed above does not indicate "PAID" a code or an asterisk (\*) will appear in the "status" column. Where an asterisk (\*) appears, the codes are set out below by the related item number. An explanation of the codes indicated in the "status" column and as set out below by the related item number appears on the reverse of the maintenance fee statement.

ITM  
NBR

ATTY DKT  
NUMBER

1 1579

DIRECT THE RESPONSE TOGETHER WITH ANY QUESTIONS ABOUT THIS NOTICE TO:  
COMMISSIONER OF PATENTS AND TRADEMARKS, BOX M. FEE, WASHINGTON, DC 20231



3-V Chemical Corporation  
P.O. Drawer Y  
Georgetown, South Carolina 29442  
(803) 546-8556

# PURCHASE ORDER

ORDER NO. 18048

PAGE 1 of 3

12/27 to 12/28/89

verbal results. Expect report  
1st week in Jan.

SPRINGBORN LABORATORIES  
TO: ONE SPRINGBORN CENTER  
ENFIELD, CT 06082-4899

SHIP  
TO:

3-V Chemical Corporation  
Pennyroyal Road  
Georgetown, S.C. 29440

(203) 749-8371

PLEASE ENTER OUR ORDER PER THE TERMS, CONDITIONS AND SPECIFICATIONS SET FORTH OR REFERRED TO ON THE FACE. ACKNOWLEDGE YOUR ACCEPTANCE BY RETURN MAIL. TRANSPORTATION CHARGES ON INVOICE MUST BE SUPPORTED BY PAID TRANSPORTATION BILLS. DO NOT INSURE PARCEL POST SHIPMENTS OR DECLARE EXCESS VALUATION ON EXPRESS FOR OUR ACCOUNT. SEND INVOICES IN QUADRUPPLICATE.

DATE OF ORDER	DELIVERY REQUIRED	SHIP VIA	F.O.B.	TERMS
11/2/89	12/14/89	NA	NA	NET 30

QUANTITY	DESCRIPTION
1)	ANALYTICAL METHOD DEVELOPMENT TO DETERMINE THE CONCENTRATION OF UVASORB HA88 IN AQUEOUS ETHANOL SOLUTIONS USING HPLC TO MINIMUM LEVELS OF 50 PARTS PER BILLION. THE ESTIMATED TIME TO COMPLETE THIS STUDY IS 20 HOURS @ \$100/HR.
2)	MIGRATION STUDY INCLUDING EXTRACTION, SAMPLING ANALYTICAL CHEMISTRY, VALIDATION, AND FINAL REPORT WHICH INCLUDES ANALYTICAL CHEMISTRY AND ALL EXTRACTION RESULTS.  THE EXTRACTIONS SHALL BE CONDUCTED AS FOLLOWS: 1) EXTRACTION ANALYSES IN 88 ETHANOL IN WATER AND 95% ETHANOL IN WATER, CONDITIONS B, C, AND D, WITH HIGH DENSITY POLYETHYLENE CONTAINING 0.3% UVASORB HA88, IN QUADRUPPLICATE.  2) EXTRACTION ANALYSES IN 88 ETHANOL IN WATER AND 95% ETHANOL IN WATER, CONDITIONS B, C, AND D WITH LOW DENSITY POLYETHYLENE CONTAINING 0.3% UVASORB HA88, IN QUADRUPPLICATE.

OUR CODE NUMBER, PURCHASE ORDER NUMBER AND NET WEIGHT MUST BE STENCILED ON TOP AND SIDES OF DRUMS AND ENDS OF SIDES OF BAGS. FREIGHT BILLS, BILLS OF LADING, QUALITY REPORTS, INVOICES AND PACKING SLIPS MUST SHOW OUR CODE NUMBER, PURCHASE ORDER NUMBER, REQUEST FOR NUMBER AND NET WEIGHT. EACH OF OUR INVOICES SHALL BEAR THE FOLLOWING STATEMENT: "WE HEREBY CERTIFY THAT THESE GOODS AND/OR SERVICES WERE PRODUCED AND/OR PERFORMED IN COMPLIANCE WITH ALL APPLICABLE REQUIREMENTS OF SECTIONS 7 AND 12 OF THE NATIONAL LABOR STANDARDS ACT OF 1938, AS AMENDED, AND OF REGULATIONS AND ORDERS OF THE ADMINISTRATION THEREOF AND OUR DIVISION ISSUED UNDER SECTION 4 THEREOF."

JOB NO.	REQUEST NO.	CHARGE DEPT.
C100001-04-001	04-001	
CORRESPONDENCE PERTAINING TO THIS ORDER SHOULD BE ADDRESSED TO THE ATTENTION OF:		TAX STATUS
JOHN SPRINGBORN		



3-V Chemical Corporation  
P.O. Drawer Y  
Georgetown, South Carolina 29442  
(803) 546-8556

# PURCHASE ORDER

ORDER NO. 13043

RELEASE NO.

PAGE 2

of 3

12/27 to 12/28/89

verbal results. Expect report  
1st week in Jan.

SPRINGBORN LABORATORIES  
TO: ONE SPRINGBORN CENTER  
ENFIELD, CT 06082-4899

SHIP  
TO:

3-V Chemical Corporation  
Pennyroyal Road  
Georgetown, S.C. 29440

(203) 749-8371

PLEASE ENTER OUR ORDER PER THE TERMS, CONDITIONS AND SPECIFICATIONS SET FORTH OR REFERRED TO ON THE FACE. ACKNOWLEDGE YOUR ACCEPTANCE BY RETURN MAIL. TRANSPORTATION CHARGES ON INVOICE MUST BE SUPPORTED BY PAID TRANSPORTATION BILLS. DO NOT INSURE PARCEL POST SHIPMENTS OR DECLARE EXCESS VALUATION ON EXPRESS FOR OUR ACCOUNT. SEND INVOICES IN QUADRUPLICATE.

DATE OF ORDER	DELIVERY REQUIRED	SHIP VIA	F.O.B.	TERMS
11/2/89	12/14/89	NA	NA	NET 30
QUANTITY	DESCRIPTION			
	III) EXTRACTION ANALYSES IN 8% ETHANOL IN WATER AND 95% ETHANOL IN WATER, CONDITIONS A, B AND C WITH POLYPROPYLENE CONTAINING 0.3% UVASORB HA88, IN QUADRUPLICATE,			
	WHERE : CONDITION A IS 250°F FOR 2 HOURS THEN 120°F TO A TOTAL OF 240 HOURS, CONDITION B IS 212°F FOR 2 HOURS THEN 120°F TO A TOTAL OF 240 HOURS, CONDITION C IS 212°F FOR 30 MINUTES THEN 120°F TO A TOTAL OF 240 HOURS.			
	SAMPLING WITH VALIDATION SHALL BE DONE FOR EACH POLYMER, SOLVENT, CONDITION AT THE END OF THE HIGH TEMPERATURE CONDITION AND THEREAFTER AT HOURS 24, 96 AND 240. VALIDATION OF EACH SAMPLE SHALL BE DONE IN TRIPLICATE.			
	THE ANALYTICAL METHOD DEVELOPMENT, CHEMICAL ANALYSES INCLUDING VALIDATION AND THE EXTRACTION WORK SHALL BE CONDUCTED IN CONFORMANCE TO THE FDA GUIDELINES RECOMMENDATIONS FOR CHEMISTRY DATA FOR INDIRECT FOOD ADDITIVE			

OUR CODE NUMBER, PURCHASE ORDER NUMBER AND NET WEIGHT MUST BE STENCILED ON TOP AND SIDES OF DRUMS AND ENDS OR SIDES OF BAGS. FREIGHT BILLS, BILLS OF LADING, QUALITY REPORTS, INVOICES AND PACKING SLIPS MUST SHOW OUR CODE NUMBER, PURCHASE ORDER NUMBER, REQUISITION NUMBER AND NET WEIGHT.

EACH OF YOUR INVOICES SHALL BEAR THE FOLLOWING STATEMENT: "WE HEREBY CERTIFY THAT THESE GOODS AND/OR SERVICES WERE PRODUCED AND/OR PERFORMED IN COMPLIANCE WITH ALL APPLICABLE REQUIREMENTS OF SECTION 6, 7, and 12 OF THE FAIR LABOR STANDARDS ACT OF 1938, AS AMENDED, AND OF REGULATIONS AND ORDERS OF THE ADMINISTRATOR OF THE WAGE AND HOUR DIVISION ISSUED UNDER SECTION 14 THEREOF."

DEL TO DEPT.	BLDG.	CHARGE DEPT.	ACCT.	REQUISITION APPROVED BY
JOB NO. C148-85-04-03			REQUEST NO. 6843	

CORRESPONDENCE PERTAINING TO THIS ORDER SHOULD BE ADDRESSED TO THE ATTENTION OF:

JOHN SCHROEDER





3-V Chemical Corporation  
P.O. Drawer Y  
Georgetown, South Carolina 29442  
(803) 546-8556

# PURCHASE ORDER

ORDER NO. 13043

RELEASE NO.

PAGE 3 of 3

12/27 to 12/28/89

related results. Expect report soon.

TO: SPRINGBORN LABORATORIES  
ONE SPRINGBORN CENTER  
ENFIELD, CT 06082-4899

SHIP  
TO:

3-V Chemical Corporation  
Pennyroyal Road  
Georgetown, S.C. 29440

(203) 749-8371

PLEASE ENTER OUR ORDER PER THE TERMS, CONDITIONS AND SPECIFICATIONS SET FORTH OR REFERRED TO ON THE FACE. ACKNOWLEDGE YOUR ACCEPTANCE BY RETURN MAIL. TRANSPORTATION CHARGES ON INVOICE MUST BE SUPPORTED BY PAID TRANSPORTATION BILLS. DO NOT INSURE PARCEL POST SHIPMENTS OR DECLARE EXCESS VALUATION ON EXPRESS FOR OUR ACCOUNT. SEND INVOICES IN QUADRUPPLICATE.

DATE OF ORDER	DELIVERY REQUIRED	SHIP VIA	F.O.B.	TERMS
11/2/89	12/14/89	NA	NA	NET 30
QUANTITY	DESCRIPTION			
	PETITIONERS. THE FINAL REPORT OF THE STUDY SHALL BE PREPARED TO INCLUDE A DESCRIPTION OF THE ANALYTICAL METHODS FOR DETERMINATION OF UVASORB HA88 CONCENTRATION IN THE FOOD SIMULANT AND IN THE POLYMER FILMS USED IN THE STUDY. THE FINAL REPORT SHALL ALSO INCLUDE THE EXTRACTION STUDY RESULTS AND ALL SUPPORTING DATA AND GRAPHS. THIS FINAL REPORT SHALL BE PREPARED FOR THE PURPOSE OF INCLUSION IN THE FDA PETITION.			
	SHOULD FDA REFUSE TO ACCEPT ANY PORTION OF THIS STUDY DUE TO THE QUALITY OF THE LABORATORY DATA AS PRESENTED IN THE PETITION, SPRINGBORN SHALL REPEAT THAT PORTION OF THE STUDY AT NO EXTRA CHARGE TO 3-V CHEMICAL.			
	INITIATION OF THIS STUDY SHALL BE CONSIDERED ACKNOWLEDGMENT BY SPRINGBORN OF THESE CONDITIONS.			

OUR CODE NUMBER, PURCHASE ORDER NUMBER AND NET WEIGHT MUST BE STENCILED ON TOP AND SIDES OF DRUMS AND ENDS OR SIDES OF BAGS. FREIGHT BILLS, BILLS OF LADING, QUALITY REPORTS, INVOICES AND PACKING SLIPS MUST SHOW OUR CODE NUMBER, PURCHASE ORDER NUMBER, REQUESTION NUMBER AND NET WEIGHT.

EACH OF YOUR INVOICES SHALL BEAR THE FOLLOWING STATEMENT: "WE HEREBY CERTIFY THAT THESE GOODS AND/OR SERVICES WERE PRODUCED AND/OR PERFORMED IN COMPLIANCE WITH ALL APPLICABLE REQUIREMENTS OF SECTION 6, 7, 8, 9, 10, 11, 12 OF THE FAIR LABOR STANDARDS ACT OF 1938 AS AMENDED AND OF REGULATIONS AND ORDERS OF THE ADMINISTRATOR OF THE WAGE AND HOUR DIVISION ISSUED UNDER SECTION 14 THEREOF."

DEL TO DEPT.	BLDG.	CHARGE DEPT.	ACCT.	REQUESTION APPROVED BY
JOB NO. C148-03-04-03			REQUEST NO. 6543	

CORRESPONDENCE PERTAINING TO THIS ORDER SHOULD BE ADDRESSED TO THE ATTENTION OF:

JOHN SCHROEDER

# CALCULATION OF LENGTH OF PATENT TERM EXTENSION FOR A FOOD OR COLOR ADDITIVE

1. ENTER THE NUMBER OF DAYS FOR THE TESTING PHASE AS DEFINED IN 37 CFR 1.776(c) (1)	688	
2. ENTER THE NUMBER OF DAYS FOR THE APPROVAL PHASE AS DEFINED IN 37 CFR 1.776(c) (2)	2,792	
3. ADD LINE 1 AND LINE 2 AND ENTER THE TOTAL HERE		3,480
4. ENTER THE NUMBER OF DAYS OF THE PERIOD OF LINE 2 WHICH OCCURRED PRIOR TO THE ISSUE DATE OF THE PATENT	0	
5. ENTER THE NUMBER OF DAYS OF THE PERIOD OF LINE 2 DURING WHICH THE APPLICANT FAILED TO ACT WITH DUE DILIGENCE AS DEFINED IN 37 CFR 1.776(d) (1) (ii)	0	
6. ADD LINE 4 AND LINE 5 AND ENTER THE TOTAL HERE		0
7. SUBTRACT LINE 6 FROM LINE 3 AND ENTER THE DIFFERENCE HERE (IF LESS THAN ZERO ENTER "0")		3,480
8. ENTER THE NUMBER OF DAYS OF THE PERIOD OF LINE 1 WHICH OCCURRED PRIOR TO THE ISSUE DATE OF THE PATENT	0	
9. ENTER THE NUMBER OF DAYS OF THE PERIOD OF LINE 1 DURING WHICH THE APPLICANT FAILED TO ACT WITH DUE DILIGENCE AS DEFINED IN 37 CFR 1.776(d) (1) (ii)	0	
10. ADD LINE 8 AND LINE 9 AND ENTER THE TOTAL HERE		0
11. SUBTRACT LINE 10 FROM LINE 7 AND ENTER THE DIFFERENCE HERE		3,480
12. ENTER THE NUMBER OF DAYS FROM LINE 1	688	
13. ENTER THE NUMBER OF DAYS FROM LINE 10	0	
14. SUBTRACT LINE 13 FROM LINE 12 AND ENTER THE DIFFERENCE HERE (IF LESS THAN ZERO ENTER "0")		
15. MULTIPLY LINE 14 BY 0.5 (ONE HALF) AND ENTER THE AMOUNT HERE		344
16. SUBTRACT LINE 15 FROM LINE 11 AND ENTER THE DIFFERENCE HERE (IF LESS THAN ZERO ENTER "0")		3,136
17. ENTER THE ORIGINAL EXPIRATION DATE OF THE PATENT	04/28/03	
18. ENTER THE EXPIRATION DATE OF PATENT IF EXTENDED BY THE NUMBER OF DAYS ON LINE 16	11/23/11	
19. ENTER THE DATE OF THE FDA (FOOD AND DRUG ADMINISTRATION) FINAL APPROVAL	05/14/99	
20. LIMITATION SET FORTH IN 37 CFR 1.776(d) (3)	14 YEARS	
21. ADD THE NUMBER OF YEARS ON LINE 20 TO THE DATE ON LINE 19 AND ENTER THE REVISED DATE HERE	05/14/13	
22. ENTER THE EARLIER DATE APPEARING ON LINE 18 OR LINE 21		11/23/11
23. ENTER THE ORIGINAL EXPIRATION DATE OF THE PATENT (FROM LINE 17)	04/28/03	
24. CHECK ONE OF THE FOLLOWING THREE BOXES AND ENTER THE LISTED TIME PERIOD HERE	5 years	
<input checked="" type="checkbox"/> THE PATENT ISSUED AFTER 09/24/84	5 YEARS	
<input type="checkbox"/> THE PATENT ISSUED PRIOR TO 09/24/84 AND NO REQUEST FOR EXEMPTION AS DEFINED IN 37 CFR 1.776(d) (6) (i) WAS FILED PRIOR TO 09/24/84	5 YEARS	
<input type="checkbox"/> THE PATENT ISSUED PRIOR TO 09/24/84 AND AN EXEMPTION AS DEFINED IN 37 CFR 1.776(d) (6) (ii) WAS FILED PRIOR TO 09/24/84	2 YEARS	
25. ADD THE NUMBER OF YEARS ON LINE 24 TO THE DATE ON LINE 23 AND ENTER THE REVISED DATE HERE	04/28/08	
26. ENTER THE EARLIER DATE APPEARING ON LINE 22 OR LINE 25		04/28/08
27. ENTER THE ORIGINAL EXPIRATION DATE OF THE PATENT (FROM LINE 17)		04/28/03
28. ENTER THE NUMBER OF DAYS BY WHICH LINE 26 AND LINE 27 DIFFER HERE THIS IS THE LENGTH OF PATENT TERM EXTENSION		1,827

PAGE: 1

PATENT NUMBER: 4477615

SERIAL NUMBER: 06/483092

ISSUE DATE: 10/16/84

FILING DATE: 04/08/83

TITLE: POLYPIPERIDINYL STABILIZING AGENTS FOR POLYMER MATERIALS

APPLICANT: RASPANTI, GIUSEPPE ; FOSSATI, NORBERTO

REEL: 4131 FRAME: 0316 DATE RECORDED: 04/08/83 , NUMBER OF PAGES: 001

ASSIGNOR: RASPANTI, GIUSEPPE

EXC DATE: 03/15/83

FOSSATI, NORBERTO

EXC DATE: 03/15/83

ASSIGNEE: APITAL PRODUZIONI INDUSTRIALI S.P.A., 6, PRINCIPESSA CLOTILD  
E SQ., MILAN (ITALY)

BRIEF: ASSIGNMENT OF ASSIGNORS INTEREST.

PRESS XMIT FOR NEXT PAGE OR FOR A SPECIFIC PAGE  
ENTER PAGE NUMBER (2 DIGITS MAX.), PRESS XMIT

06/17/99 14:30  
PAGE: 2

RETURN ADDRESS: LAW OFFICE

WALTER H. SCHNEIDER

P. O. BOX 20349

COLUMBUS, OH 43220

REEL: 5581 FRAME: 0912 DATE RECORDED: 02/01/91 NUMBER OF PAGES: 008

ASSIGNOR: APITAL PRODUZIONI INDUSTRIALI S.P.A.

EXC DATE: 11/06/90

ASSIGNEE: DESITALIA S.P.A., MILANO (MI) PIAZZALE PRINCIPESSA CLOTILDE  
6, 20100

BRIEF: MERGER (SEE DOCUMENT FOR DETAILS).

MARCH 29, 1986 - ITALY

RETURN ADDRESS: WALTER H. SCHNEIDER

P.O. BOX 917

DUBLIN, OH 43017

06/17/99 14:30

PRESS XMIT FOR NEXT PAGE OR FOR A SPECIFIC PAGE  
ENTER PAGE NUMBER (2 DIGITS MAX.), PRESS XMIT

PAGE: 3

REEL: 6353 FRAME: 0791 DATE RECORDED: 12/02/92 NUMBER OF PAGES: 006

ASSIGNOR: DESITALIA PARTECIPAZIONI

EXC DATE: 10/16/92

ASSIGNEE: 3V PARTECIPAZIONI INDUSTRIALI S.P.A.  
PIAZZALE PRINCIPESSA, CLOTILDE, 6  
MILAN, ITALY

BRIEF: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).  
EFFECTIVE ON 10/16/1992

RETURN ADDRESS: WALTER H. SCHNEIDER  
ATTORNEY AT LAW  
P.O. BOX 917  
DUBLIN, OH 43017

\*\*\* LAST PAGE \*\*\* ENTER PAGE NUMBER (2 DIGITS MAX.)  
AND PRESS XMIT TO GO BACK TO DESIRED PAGE

06/17/99 14:30

11 1856V  
1579

ASSIGNMENT  
UNITED STATES OF AMERICA

Whereas, X/we (1) 1) Giuseppe Raspanti. - 2) Norberto Fossati

of (2) (1) and (2) 28, Moro Street, Mozzo (Bergamo) (Italy)

have invented certain new and useful improvements in (3) "STABILIZING AGENTS FOR POLYMER MATERIALS"  
for which application for

Letters Patent in the United States of America (4) is about to be made:  
has been made

And Whereas, (5) APITAL PRODUZIONI INDUSTRIALI s.p.a.  
of (6) 6, Principessa Clotilde Square, Milan (Italy) is/are  
desirous of acquiring an interest therein and in the Letters Patent to be obtained therefor;

Now Therefore, be it known by all whom it may concern, that for good and valuable consideration (the  
sufficiency of which is hereby acknowledged) I/we have assigned, transferred and set over, and by these  
presents do assign, transfer and set over unto the said (5) APITAL PRODUZIONI INDUSTRIALI s.p.a.

for the territory of the United States of America, and not elsewhere; the full and exclusive right, title, and  
interest in and to the said invention, as fully set forth and described in the specification

(7) prepared and executed by me/us on (8) March 15, 1983

filed in the U.S. Patent Office under Ser. No. (9) on (10)

preparatory to obtaining Letters Patent therefor; said invention, application and Letters Patent to be held and  
enjoyed by the said (5) APITAL PRODUZIONI INDUSTRIALI s.p.a.

to the full end of the term for  
which said Letters Patent are granted, as fully and entirely as the same would have been held by me/us had  
this assignment and transfer not been made.

In testimony whereof, I/we have hereunto set my/our hand this  
(11) 15th day of March 19 83.

WITNESSES:

INVENTOR(S):

*Giuseppe Raspanti*

RECORDED  
PATENT & TRADE MARK DIV.

*Raspanti, Giuseppe*

APR - 8 1983

*N. Fossati*

REL 4 | 3 | FILE 3 | 6

RECORDATION FORM COVER SHEET  
PATENTS ONLY

U.S. DEPARTMENT OF COMMERCE  
Patent and Trademark Office

Tab settings 40 40



To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):  
Desitalia Partecipazioni  
Industriali S.p.A., also  
known as Desitalia S.p.A.  
Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

2. Name and address of receiving party(ies):  
Name: 3V Partecipazioni Industriali  
Internal Address: S.p.A.

3. Nature of conveyance: 14  
☒ Assignment ☐ Merger  
☐ Security Agreement ☒ Change of Name  
☐ Other \_\_\_\_\_

Street Address: Piazzale Principessa  
Clotilde, 6

City: Milan State: Italy ZIP: \_\_\_\_\_

Execution Date: 16 October 1992

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is:

A. Patent Application No.(s)

B. Patent No.(s)

4,477,615  
4,530,950

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: \_\_\_\_\_

Internal Address: \_\_\_\_\_

WALTER H. SCHNEIDER  
ATTORNEY-AT-LAW  
P. O. BOX 917  
DUBLIN, OHIO 43017

Street Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_

6. Total number of applications and patents involved: 2

7. Total fee (37 CFR 3.41): \$ 80

☒ Enclosed

☐ Authorized to be charged to deposit account

8. Deposit account number: \_\_\_\_\_

(Attach duplicate copy of this page if paying by deposit account)

179 HP 12/08/92 4477615

DO NOT USE THIS SPACE

2 581

80.00 CK.

9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Walter H. Schneider

Name of Person Signing

ATTY DAK. 1554, 1574

91652367

Signature

Nov. 30, 1992

Date

Total number of pages comprising cover sheet: 1

OMB No. 0651-0011 (exp. 4/94)

Do not detach this portion

Mail documents to be recorded with required cover sheet information to:

Commissioner of Patents and Trademarks  
Box Assignments  
Washington, D.C. 20231

Public burden reporting for this sample cover sheet is estimated to average about 30 minutes per document to be recorded, including time for reviewing the document and gathering the data needed, and completing and reviewing the sample cover sheet. Send comments regarding this burden estimate to the U.S. Patent and Trademark Office, Office of Information Systems, PK2-1000C, Washington, D.C. 20231, and to the Office of Management and Budget, Paperwork Reduction Project (0651-0011), Washington, D.C. 20503.

REEL FRAME  
5358 0791



CAMERA DI COMMERCIO  
INDUSTRIA ARTIGIANATO E AGRICOLTURA  
DI MILANO

N. 427828 0922920128 12/10/1992 MILANO 16 OTTOBRE 1992

GI CERTIFICAZIONE

DAL REGISTRO DELLE DITTE DI MILANO

TENUTO AI SENSI DELLA LEGGE QUANTO SEGUE SULL'IMPRESA SOTTOINDICATA

NUMERO DI ISCRIZIONE 238429

DATA DI ISCRIZIONE 11/02/1986

DEGNOMAZIONE

SU PARTECIPAZIONI INDUSTRIALI S.P.A.

SEDE

MILANO

SCHIAZZALE PRINCIPESCA CLODIO DE

FORMA GIURIDICA

SOCIETA' PER AZIONI

ESTREMI ATTO COSTITUZIONE

NOTAIO (O UFFICIO DEL REGISTRO) ANSELMO DR. GIOVANNI BATTISTA

LOCALITA' BERGAMO

N. 102860

DATA 02/04/1986

ESTREMI ATTO TRASFORMAZIONE

NOTAIO (O UFFICIO DEL REGISTRO) ANSELMO DR. G.B.

LOCALITA' BERGAMO

N. 104620

DATA 02/07/1986

DATA DI FONDAZIONE

INIZIO ATTIVITA' NELLA PROVINCIA

DURATA

28/11/1984

30/06/2075

PROROGA TACITA: 5 ANNI

CAPITALE (LIRE)

13.002.400.000

OGGETTO DELL'ESERCIZIO SCOPO SOCIALE

LA SOCIETA' HA PER OGGETTO L'ACQUISTO E L'AMMINISTRAZIONE DI

PARTECIPAZIONI IN ALTRE SOCIETA' OD ENTI OPERANTI NEL TERRITORIO

ITALIANO OD ALL'ESTERO, IL FINANZIAMENTO ED IL COORDINAMENTO TECNICO

ED ENTI NEI QUALI PARTECIPA, LA

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E

LA GESTIONE DI TITOLI PUBBLICI E



A. Minchillo

6353

REEL

FRAME

0792

Le Imprese e i loro titolari sono tenuti per gli usi per i quali la legge non prescrive il bollo, a conservare in originale e in copia i documenti dell'iscrizione e dell'iscrizione al Registro.

Le Imprese e i loro titolari sono tenuti per gli usi per i quali la legge non prescrive il bollo, a conservare in originale e in copia i documenti dell'iscrizione e dell'iscrizione al Registro.



CAMERA DI COMMERCIO  
INDUSTRIA ARTIGIANATO E AGRICOLTURA  
DI MILANO

SEGUITO DEL CERTIFICATO N. 429828

PAG. 2

NATO IL 01/07/1932 A BERGAMO  
DATA INIZIO CARICA 30/01/1990  
SECCOMANDI CARLO

\*PRESIDENTE CONSIGLIO DI AMMINI  
DURATA 3 ANNI

NATO IL 05/02/1941 A BERGAMO  
DATA INIZIO CARICA 30/03/1990  
SECCOMANDI ENRICO

\*CONSIGLIERE DELEGATO  
DURATA 3 ANNI

NATO IL 16/05/1956 A BERGAMO  
DATA INIZIO CARICA 30/03/1990  
JONES JOHN FRANCIS AVERX

\*CONSIGLIERE DELEGATO  
DURATA 3 ANNI

NATO IL 05/04/1940 A BROMLEY  
DATA INIZIO CARICA 30/01/1990  
BARONNI NICOLETTA

\*CONSIGLIERE  
DURATA 3 ANNI

NATO IL 29/08/1949 A BERGAMO  
DATA INIZIO CARICA 30/01/1990  
VAN HOORN JACOB

\*CONSIGLIERE  
DURATA 3 ANNI

NATO IL 23/11/1920 A LUGO  
DATA INIZIO CARICA 30/01/1990  
P. IL

\*CONSIGLIERE  
DURATA 3 ANNI

I PRESENTE CERTIFICATO

BOLLO L. 15000  
DIRITTI L. 7000  
TOTALE L. 22000

CAMERA DI COMMERCIO INDUSTRIA  
ARTIGIANATO E AGRICOLTURA DI MILANO



5353

REEL

NOTIZIA - con atto in data 16/12/1991 venne modificata la denominazione da "DESITALIA PARTECIPAZIONI INDUSTRIALI S.P.A." in "3V PARTECIPAZIONI INDUSTRIALI S.P.A."

Postilla approvata  
Milano 19/10/1992



IL SEGRETARIO GENERALE  
(Berto Boschetto)

(G. Milano)

FRAME



CHAMBER OF COMMERCE INDUSTRY HANDICRAFT AND AGRICULTURE OF MILAN

no. 429685 0912920128 1238429 VD29

MILAN, 16 OCTOBER 1992

IT IS HEREBY CERTIFIED AS RESULTING FROM THE REGISTRY OF =====  
COMPANIES OF MILAN ACCORDING TO THE ITALIAN LAW, WHAT FOLLOWS ==  
ABOUT THE COMPANY MENTIONED BELOW =====

REGISTRATION no. 1238429 REGISTRATION DATE 11.03.1987 =====

CORPORATE NAME =====

== = 3V PARTECIPAZIONI INDUSTRIALI S.P.A. =====

PLACE OF BUSINESS =====

== = MILAN =====

== = PIAZZALE PRINCIPESSA CLOTILDE, 6 =====

TYPE OF COMPANY =====

== = JOINT-STOCK COMPANY =====

DATE ON ARTICLES OF INCORPORATION =====

== = NOTARY PUBLIC (OR REGISTER OFFICE) ANSELMO DR. G.B. =====  
== = PLACE BERGAMO no. 102860 DATE 02/04/1986 =====

DATE ON ARTICLES OF TRANSFORMATION =====

== = NOTARY PUBLIC (OR REGISTER OFFICE) ANSELMO DR. G.B. =====  
== = PLACE BERGAMO no. 104620 DATE 02/07/1986 =====

DATE OF FOUNDATION      ACTIVITY BEGINNING IN PROVINCE      DURATION  
-- -- --      28/11/1986      30/06/2075

-----      -----      EXTENDED  
-----      -----      OF 5 YEARS

CAPITAL (LIRA) =====  
= = = 16,002,400,000 =====

OBJECT OF THE FIRM OR SOCIAL SCOPE =====  
SALE AND ADMINISTRATION OF SHARINGS IN OTHER COMPANIES OR  
ORGANIZATIONS OPERATING IN THE ITALIAN TERRITORY OR ABROAD. THE  
FINANCING AND THE TECHNICAL CO-ORDINATION OF THE COMPANIES THEY  
HAVE SHARES IN, SALE AND OWNERSHIP AND MANAGING OF GOVERNMENT  
STOCKS AND SHARES. THEY CAN ALSO DO ALL THE OPERATIONS FINANCIAL  
OPERATIONS RELATING TO MOVABLE GOODS AND REAL ESTATE, LEASING  
OPERATIONS THAT WILL BE DEEMED TO BE USEFUL OR NECESSARY TO  
REACH THE SOCIAL SCOPE; THEY CAN ALSO GRANT WARRANTIES

6353

0794

REEL  
FRAME

CONCERNING OBLIGATIONS FROM THIRD PARTIES EVEN NOT PARTNERS.  
THEY CAN CARRY OUT SERVICES IN FAVOUR OF THE COMPANIES BELONGING  
TO THE SAME GROUP, INCLUDING PAYMENT OF DEBTS AND COLLECTION OF  
CREDITS. =====

POWERS, DELEGATE LIMITS, GENERAL SIGNATURE CAPABILITY, OR FROM  
STATUTE =====

THE SOLE ADMINISTRATOR OR THE BOARD OF DIRECTORS HAVE ALL  
THE POWERS OF ORDINARY AND EXTRAORDINARY ADMINISTRATION, WITH NO  
LIMITS. =====

BOARD OF DIRECTORS-DIRECTORS =====

SECCOMANDI ANTONIO =====

= = BORN ON 01/07/1932 AT BERGAMO PRESIDENT OF BOARD OF = = =

= = = = = DIRECTORS =====

= = ACTIVITY BEGINNING 30/01/1990 DURATION 3 YEARS =====

SECCOMANDI CARLO =====

= = BORN ON 05/02/1961 AT BERGAMO MANAGING DIRECTOR =====

= = ACTIVITY BEGINNING 30/03/1990 DURATION 3 YEARS =====

SECCOMANDI ENRICO=====

= = BORN ON 16/06/1956 AT BERGAMO MANAGING DIRECTOR =====

= = ACTIVITY BEGINNING 30/03/1990 DURATION 3 YEARS =====

JONES JOHN FRANCIS AVERY =====

= = BORN ON 05/04/1990 AT BROMLEY DIRECTOR =====

= = ACTIVITY BEGINNING 30/01/1990 DURATION 3 YEARS =====

SARONNI NICOLETTA =====

= = BORN ON 29/08/1949 AT BERGAMO DIRECTOR =====

= = ACTIVITY BEGINNING 30/01/1990 DURATION 3 YEARS =====

VAN HOORN JACOB =====

= = BORN ON 23/11/1920 AT THE HAGUE DIRECTOR =====

= = ACTIVITY BEGINNING 30/01/1990 DURATION 3 YEARS =====

THIS CERTIFICATE HAS ISSUED WITH STAMPS.=====

p. THE GENERAL SECRETARY - BENITO BOSCHETTO - THE OFFICER IN  
CHARGE - signature - seal of the Chamber of Commerce, Industry  
and Handicraft - Milan. =====

STAMP Lit. 15000 - RIGHTS Lit. 7000 - TOTAL Lit. 22000 =====

NOTE: by means of an act dated 16/12/1991 the company name was  
changed from "DESITALIA PARTECIPAZIONI INDUSTRIALI SPA or  
briefly DESITALIA SPA" into "3V PARTECIPAZIONI INDUSTRIALI  
S.P.A." - Postille approved - Milan, 19/10/1992 - Seal of the  
Chamber of Commerce, Industry, Handicraft and Agriculture- Milan  
- p. The General Secretary, (Benito Boschetto) signature  
(G.Milani). =====

REEL FRAME

0795

I, Dino Citelli,  
of Via Bramante, 5 - Milano - Italy herewith declare  
that I well understand the English and the Italian  
languages and that the foregoing is a full, true and  
faithful translation of the Extract from the Company  
Registry issued by the Chamber of Commerce, Industry,  
Handicraft and Agriculture of Milan, made by me on  
23 November 1992.

and attached thereto

Milan, 23 November 1992

Signature: *Dino Citelli*

RECORDED  
PATENT AND TRADEMARK  
OFFICE

DEC -2 1992

6353

REEL

0798

FRAME



#16.00 578  
A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BOX ASSIGNMENTS  
COMMISSIONER OF PATENTS AND TRADEMARKS  
WASHINGTON, D.C. 20231

Sir:

Submitted herewith for recordal is an Extract from the Registry of Companies, issued by the Chamber of Commerce, Industry and Handicraft, Bergamo, Italy, together with an English translation, certifying to the merger (see page 2 of the Extract) of APITAL PRODUZIONI INDUSTRIALI S.P.A., a corporation of Italy with offices in Milan, Italy into DESITALIA S.P.A. a corporation of Italy with offices in Milan, Italy.

Recordal of this Extract reflecting the change, resulting from this merger, in the ownership of the following U.S. patent is requested:

USP 4,477,615  
October 16, 1984  
Reel/Frame 4131/0316

USP 4,530,950  
July 23, 1985  
Reel/Frame 4087/0176

RECEIVED  
FEB-6 AM 7:51  
ASSIGNMENT BRANCH

REC 5581 FRAM 912

A check in the amount of \$16 representing the fee for recordal with respect to two properties is enclosed.

Please return the original document to:

91558044

Walter H. Schneider  
P.O. Box 917  
Dublin, Oh. 43017

Respectfully submitted,

Walter H. Schneider  
Attorney of Record

WHS:vr  
Tel: 614-889-5747  
Atty Dock. 1579 and 1559

050 10 02400491 4477615  
WALTER H. SCHNEIDER  
ATTORNEY AT LAW  
P. O. BOX 917  
DUBLIN, OHIO 43017

2 518 16.00 CK

4-5 4,477,615  
4,530,950  
4-5 4,530,950

VERIFICATION OF TRANSLATION

I, Elena Morandi,  
of Via G.Mameli, 6 - Busto Arsizio (Varese) - Italy,  
do solemnly and sincerely declare that I am acquainted with the English and the Italian languages and that the following is a true translation into English language of the extract of the Registry of Companies issued by the Chamber of Commerce, Industry and Handicraft.

Signature:

*Elena Morandi*

WALTER H. SCHNEIDER  
ATTORNEY AT LAW  
P. O. BOX 917  
DUBLIN, OHIO 43017

REEL 5581 FRAME 913

CHAMBER OF COMMERCE INDUSTRY HANDICRAFT AND AGRICULTURE OF BERGAMO

11/6/90

PAGE 1

FROM THE FILES OF

THE REGISTER OF COMPANIES HOLD BY THE CHAMBER OF COM-  
MERCE INDUSTRY HANDICRAFT AND AGRICULTURE OF BERGAMO ACCORDING TO THE  
LAW, RESULTS WHAT FOLLOWS ABOUT THE COMPANY MENTIONED BELOW:

REC 5581 FRAME 914

REGISTRATION R.D.N. 230523 OF SEPTEMBER 8, 1986

TYPE OF COMPANY : JOINT-STOCK COMPANY

CORPORATE NAME : DESITALIA PARTECIPAZIONI INDUSTRIALI S.P.A. (OR  
BRIEFLY "DESITALIA S.P.A.")

PLACE OF BUSINESS : MILANO (MI) PIAZZALE PRINCIPESSA CLOTILDE 6

ZIP CODE 20100 FISCAL CODE : 01687740165

- DATE OF FOUNDATION: APRIL 2, 1986 TERM: JUNE 30, 2075

DOCUMENT UNDER THE SEAL OF A PUBLIC OFFICER, DRAFTED BY THE NOTARY  
PUBLIC, DR. G.B. ANSELMO

RECORD NO. 102860 PLACE BERGAMO (BG)

-COMPANY'S CAPITAL -

DELIBERATED: 16,002,400,000 UNDERWRITTEN: 16,002,400,000 PAID-UP: 16,002,400,000

TRANSFORMATION FROM LIMITED PARTNERSHIP TO A JOINT-STOCK COMPANY ON  
JULY 2, 1986 WITH A DOCUMENT UNDER THE SEAL OF A PUBLIC OFFICER DRAFTED  
BY THE NOTARY PUBLIC, DR. G.B. ANSELMO

REP/REG. 104620 OF JULY 2, 1986 PLACE BERGAMO (BG)

- NOT IN FORCE -

SOCIAL SCOPE: THE SALE AND ADMINISTRATION OF SHARINGS IN OTHER COMPANIES  
OR ORGANIZATIONS OPERATING IN THE ITALIAN TERRITORY OR ABROAD, THE FI-  
NANCING AND THE TECHNICAL CO-ORDINATION AND FINANCING AND TECHNICAL AND  
FINANCIAL CO-ORDINATION OF THE COMPANIES AND ORGANIZATIONS THEY HAVE  
SHARE IN, THE SALE, THE OWNERSHIP AND MANAGING OF GOVERNMENT STOCKS  
AND SHARES.

ACTIVITY CODE

CODE OF IMPORTANCE

DATE OF BEGINNING

813.2

P

0001) SECCOMANDI ANTONIO BORN ON JULY 1, 1932 AT BERGAMO (BG)  
- PRESIDENT LEGAL REPRESENTATIVE OF THE COMPANY  
0002) SECCOMANDI ENRICO BORN ON JUNE 16, 1956 AT BERGAMO (BG)  
- MANAGING DIRECTOR  
0003) SECCOMANDI CARLO BORN ON FEBRUARY 5, 1961 AT BERGAMO (BG)  
- MANAGING DIRECTOR  
0004) JONES JOHN FRANCIS AVERY BORN ON APRIL 5, 1940 AT BROMLEY  
(GREAT BRITAIN) - DIRECTOR  
0005) SARONNI NICOLETTA BORN ON AUGUST 29, 1949 AT BERGAMO (BG)  
- DIRECTOR  
0006) VAN HOORN JACOB BORN ON NOVEMBER 23, 1920 AT THE HAGUE  
(THE NETHERLANDS) - DIRECTOR

LOCAL UNIT NO. 0001 ADMINISTRATIVE OFFICE BERGAMO (BG)

PIAZZA DELLA LIBERTA' 10 ZIP CODE 24100

OPENING DATE : NOVEMBER 6, 1986

MERGER WITH INCORPORATION OF:

- "APITAL PRODUZIONI INDUSTRIALI S.P.A."

HEAD-OFFICE: MILANO (BG) R.D. NUMBER 125536

- "LAITHERMIK S.P.A."

HEAD-OFFICE: DALMINE (BG) R.D. NUMBER 165122

DATE OF DELIBERATION MARCH 29, 1989 DATE OF EXECUTION MAY 23, 1989

INFORMATION FROM M.A.D. REGISTER OF COMPANIES

DATE OF NOTIFICATION (MF) SEPT.8, 1986

TRANSFORMATION OF THE ALREADY EXISTING COMPANY INTO A LIMITED PART-  
NERSHIP NAMED "DESITALIA S.A.S. DI ANTONIO SECCOMANDI E C."  
FORMED BY MESSRS: SECCOMANDI ANTONIO (GENERAL PARTNER), SEC-  
COMANDI ENRICO BORN ON JUNE 16, 1956 AT BERGAMO, SECCOMANDI  
CARLO BORN ON FEBRUARY 5, 1961 AT BERGAMO AND SECCOMANDI PAUL  
MARIA ENEA BORN ON OCTOBER 26, 1979 IN NEW YORK (USA) (LIMITED  
PARTNERS), IN THE JOINT-STOCK COMPANY NAMED "DESITALIA S.P.A.";  
INCREASING IN THE COMPANY'S CAPITAL FROM LIT. 2,400,000,000  
TO LIT. 4,000,000,000 WITH AN ACT DATED JULY 2, 1986.

REC 5581 1989/15

DATE OF NOTIFICATION (MM) SEPT. 8, 1986

APPOINTMENT OF MR. WERNER WILLI AS A PROCURATOR WITH AN ACT DATED JULY 24, 1986.

DATE OF NOTIFICATION (MF) DEC. 11, 1986

CHANGE OF THE NAME FROM: "DESITALIA S.P.A." TO: "DESITALIA PARTE-  
CIPAZIONI INDUSTRIALI S.P.A." (OR BRIEFLY "DESITALIA S.P.A.");  
MOVE FROM THE HEAD-OFFICE OF BERGAMO - VIA T.TASSO, 58 TO MILAN -  
PIAZZALE PRINCIPESSA CLOTILDE, 6; CONSTITUTION OF AN ADMINISTRA-  
TIVE OFFICE AT BERGAMO - VIA T.TASSO, 58 WITH AN ACT DATED NOV.  
6, 1986.

DATE OF NOTIFICATION (MM) JUNE 23, 1989

MARCH 29, 1989 - ADJOURNMENT OF THE CASE AS PER THE FILES  
OF THE CHAMBER OF COMMERCE INDUSTRY HANDICRAFT OF MILAN

DATE OF NOTIFICATION (MM) JULY 6, 1989

MAY 23, 1989 - MERGER ACCORDING TO THE DELIBERATION OF MARCH 29,  
1989

DATE OF NOTIFICATION (MM) JUNE 7, 1990

NOV. 8, 1989 - MOVE OF A LOCAL UNIT FROM BERGAMO (BG) VIA T.TASSO  
58 ADJOURNMENT OF THE CASE ACCORDING TO THE FILES OF THE CHAMBER  
OF COMMERCE INDUSTRY HANDICRAFT OF MILAN (POSITIONS IN THE COM-  
PANY AND COMPANY'S CAPITAL). CHANGE IN THE EXCHANGE RATE OF THE  
CONVERTIBLE LOAN STOCK OF LIT. 4,000,000,000 ISSUED ON JULY 2,  
1984 FROM "SIGMA ITALIANA PRODOTTI CHIMICI SPA" AND SUBSEQUENTLY  
INCORPORATED BY DESITALIA.

\*\*\*\*\*

REEL 5581 FINAL 916



Camera di Commercio Industria Artigianato e Agricoltura di Bergamo

LI: 06/11/70

PAG. 1

VISURA CAMERALE

DAL REGISTRO DELLE DITTE, TENUTO DALLA CCIAA DI BERGAMO  
AI SENSI DI LEGGE, RISULTA QUANTO SEGUE RELATIVAMENTE ALLA DITTA SOTTO INDICATA:

ISCRIZIONE

R.D.N. 230523 DEL 08/09/1986

NATURA GIURIDICA: SOCIETA' PER AZIONI

DENOMINAZIONE: DESITALIA PARTECIPAZIONI INDUSTRIALI S.P.A. (OPPURE BREVEMENTE  
"DESITALIA S.P.A.")

SEDE: MILANO (MI) PIAZZALE PRINCIPESSA CLOTILDE 6 CAP 20100  
CODICE FISCALE: 01687740165

-DATA COSTITUZIONE: 02/04/1986 DATA TERMINE: 30/06/2075

TIPO DELL' ATTO: PUBBLICO, REDATTO DA NOTAIO

NOTAIO DOTT. G.B. ANSELMO

REPERTORIO NUM. 102860 LOC. BERGAMO (BG)

-CAPITALE SOCIALE-

DELIB.: 16.002.400.000

SOTT.: 16.002.400.000

VERS.: 16.002.400.000

TRASFORMATA DA SOCIETA' IN ACCOMANDITA SEMPLICE

IN SOCIETA' PER AZIONI IL 02/07/1986

TIPO DELL' ATTO: PUBBLICO, REDATTO DA NOTAIO

NOTAIO DOTT. G.B. ANSELMO

REP/REG. 104620

DEL 02/07/1986 LOC. BERGAMO (BG)

-INATTIVA-

OGGETTO SOCIALE: LA COMPRAVENDITA E L'AMMINISTRAZIONE DI PARTECIPAZIONI IN ALTRE  
SOCIETA' OD ENTI OPERANTI NEL TERRITORIO ITALIANO OD ALL'ESTERO, IL FINANZIAMENTO  
ED IL COORDINAMENTO TECNICO E FINANZIAMENTO ED IL COORDINAMENTO TECNICO E FINAN-  
ZIARIO DELLE SOCIETA' ED ENTI NEI QUALI PARTECIPA, LA COMPRAVENDITA, IL POSSESSO  
E LA GESTIONE DI TITOLI PUBBLICI E PRIVATI.

CODICE ATTIVITA'  
813.2

CODICE IMPORTANZA  
P

DATA INIZIO

0001) SECCOMANDI ANTONIO

NATO A: BERGAMO (BG) IL 01/07/1932

-PRESIDENTE

LEGALE RAPPRESENTANTE DI SOCIETA'

0002) SECCOMANDI ENRICO

NATO A: BERGAMO (BG) IL 16/06/1956

-CONSIGLIERE DELEGATO

0003) SECCOMANDI CARLO

NATO A: BERGAMO (BG) IL 05/02/1961

-CONSIGLIERE DELEGATO

SEGUE

REC 5581-FRAN 9-1-7

Camera di Commercio Industria Artigianato e Agricoltura di Bergamo

LI: 06/11/90

PAG. 2

0004) JONES JOHN FRANCIS AVERY  
NATO A: BROMLEY STATO: GRAN BRETAGNA IL 05/04/1940  
-CONSIGLIERE

0005) SARONNI NICOLETTA  
NATA A: BERGAMO (BG) IL 29/08/1949  
-CONSIGLIERE

0006) VAN HOORN JACOB  
NATO A: AJA STATO: OLANDA IL 23/11/1920  
-CONSIGLIERE

UNITA' LOCALE N. 0001 SEDE AMMINISTRATIVA  
BERGAMO (BG) PIAZZA DELLA LIBERTA' 10 CAP 24100  
DATA APERTURA: 06/11/1986

FUSIONE MEDIANTE INCORPORAZIONE DI:  
-"APITAL PRODUZIONI INDUSTRIALI S.P.A."  
SEDE: MILANO (BG) NUMERO R.D. 125536  
-"LAITHERMIK S.P.A."  
SEDE: DALMINE (BG) NUMERO R.D. 165122  
DATA DELIBERA 29/03/1989 DATA ESECUZIONE 23/05/1989

INFORMAZIONI DEL M.A.D. REGISTRO DITTE

DATA DENUNCIA (MF) 03/07/1986

TRASFORMAZIONE DELLA PREESISTENTE SOCIETA' IN ACCOMANDITA  
SEMPLICE DENOMINATA "DESITALIA S.A.S. DI ANTONIO SECCOMANDI E  
C." COMPOSTA DAI SIGG.: SECCOMANDI ANTONIO (SOCIO  
ACCOMANDATARIO), SECCOMANDI ENRICO NATO A BERGAMO IL 16/6/1956,  
SECCOMANDI CARLO NATO A BERGAMO IL 5/2/1961 E SECCOMANDI PAUL  
MARIA ENEA NATO A NEW YORK (USA) IL 26/10/1979 (SOCC  
ACCOMANDANTI), NELLA SOCIETA' PER AZIONI DENOMINATA "DESITALIA  
S.P.A."; AUMENTO DEL CAPITALE SOCIALE DA L. 2.400.000.000 A L.  
4.000.000.000 - ATTO DEL 2/7/1986.

DATA DENUNCIA (MM) 08/09/1986

NOMINA A PROCURATORE DEL SIG. WERNER WILLI - ATTO DEL 24/7/1986.

DATA DENUNCIA (MF) 11/12/1986

MODIFICATA LA DENOMINAZIONE DA: "DESITALIA S.P.A." A: "DESITALIA  
PARTECIPAZIONI INDUSTRIALI S.P.A." (OPPURE BREVEMENTE "DESITALIA  
S.P.A."); TRASFERIMENTO DELLA SEDE DA BERGAMO - VIA T. TASSO, 58  
A MILANO - PIAZZALE PRINCIPESSA CLOTILDE, 6; ISTITUZIONE DI UNA  
SEDE AMMINISTRATIVA IN BERGAMO - VIA T. TASSO, 58 - ATTO DEL  
6/11/1986.

DATA DENUNCIA (MM) 23/06/1989

29/03/1989 - AGGIORNAMENTO PRATICA COME DA VISURA C.C.I.A.A. DI MILANO

DATA DENUNCIA (MM) 06/07/1989

23/05/1989 - FUSIONE IN ESECUZIONE DELLA DELIBERA DEL 29/03/1989

DATA DENUNCIA (MM) 07/06/1990

SEGUE

RELI 5581 FRANG 17A

Camera di Commercio Industria Artigianato e Agricoltura di Bergamo

LI: 06/11/90

PAG. 3

08/11/1989 - TRASFERIMENTO DI UN'UNITA' LOCALE DA BERGAMO (BG) VIA T. TASSO  
58 AGGIORNAMENTO PRATICA COME DA VISURA CCIA DI MILANO (CARICHE  
SOCIALI E CAPITALE SOCIALE). MODIFICA RAPPORTO DI CAMBIO  
PRESTITO OBBLIGAZIONARIO CONVERTIBILE DI LIRE 4.000.000.000  
EMESSO IN DATA 2.7.1984 DALLA " SIGMA ITALIANA PRODOTTI CHIMICI  
SPA" ED INCORPORATA SUCCESSIVAMENTE DALLA DESITALIA.

\*\*\*\*\*

REEL 5581 FRAME 918

RECORDED  
PATENT AND TRADEMARK  
OFFICE

FEB -1 1991

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**